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A System For Evaluating Spinal Fixation Devices

by

© Robert Evenson

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ABSTRACT

Internal fixation of clinically unstable thoracolumbar spinal fractures has met with mixed success using a variety of implants. A significant number of failures due to broken components or hook/screw pullout have been experienced as well as uncertain fracture reduction and protection.

In this study, an experimental method was developed for the evaluation of internal spinal fixation devices. Procedures were introduced for maintenance and preparation of relevant uniform spinal models from porcine specimens. Reproducible fracture creation was addressed and implemented with specialized jigs and loading fixtures. Testing showed the greatest motion, for the fracture model in this study, occured at the most anterior points of the fractured vertebral body during both compression and torsional loading. The largest translations were in the superior/inferior and lateral directions in the frontal plane. Relative anteroposterior motion due to shear loading was found to be negligible as was motion in the posterior region of the fractured vertebra. Accurate measurement of fracture site motion was incorporated, establishing a reliable basis for evaluation and comparison of spinal fixation device performance. Fracture site motion was recorded using a dedicated biaxial displacement transducer with its frame attached to the inferior component of the fractured vertebra and measuring the relative motion of the superior component. Maximum measurement error was 0.04 mm over a maximum range of 20 mm. For fracture types and loading regimes where three dimensional analysis is required, a system comprising three

biaxial displacement transducers is used. Specialized specimen mounting end caps were employed to ensure precise load application and end conditions. Simple experiments confirmed that attachment of the endcap was secure and precisely located on a vertebra. Intervening discs were eliminated between the end cap and first fixated vertebra to maintain positive control of end conditions throughout a loading regime. All procedures and equipment developed were highly reproducible and economized the time expended in experimental trials. In addition, acoustic emission was evaluated as a tool to monitor fracture creation and found to provide useful information. It may also be used to ensure experimental control is not lost due to further damage to the specimen during testing.

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TABLE OF CONTENTS

Chapter 1. Introduction 1

Chapter 2. Historical Review 4
2.1. Biomechanical Studies of the Intact Human Spine 4
2.2. Fracture Instability Criterion 6
2.3. Development of Posterior Spinal Fixation Devices 8
2.4. Biomechanical Testing of Posterior Spinal Fixation Devices . 9
2.5. Problems with Experiments 13

Chapter 3. Spinal Model 15
3.1. Specimen Excision, Handling and Storage 15
3.2. Anatomical Comparison of Porcine and Human Vertebra 17

Chapter 4. Fracture Creation 27
4.1. Problems With Fracture Creation 27
4.2. Development of Reproducible Fracture Model 28
4.2.1. Clinically Stable Single Vertebra (type one) Fracture Creation 29
4.2.2. Clinically Unstable Single Vertebra (type two) Fracture Creation 33
4.2.3. Multi-segment Three Column (type three) Fracture Creation 35
4.2.4. Fracture Creation Test Results 37
4.2.4.1. Type One Fracture Results 37
4.2.4.2. Type Two Fracture Results 46
4.2.4.3. Type Three Fracture Results 46
4.3. Application of Acoustic Emission to Fracture Testing . . . 51
4.3.1. Acoustic Emission Results 52

Chapter 5. Measurement of Fixation Device Effectiveness 55
5.1. Earlier Methods 55
5.2. Fundamental Basis for Evaluation of Instrumentation 56
5.3. Design Criteria for Local Measurement 58
5.4. The Transducer 61
5.5. Transducer Calibration 66
5.6. Data Acquisition 68
5.7. Testing the Transducer - Comparison with Global Measurement System 70
5.7.1. Compression Test 72
5.7.2. Torsion Test Results 72
5.8. Three Dimensional Measurement 77

Chapter 6. Development of End Caps and Loading Fixtures 80
6.1. Problems With End Cap Designs 80
6.2. End Cap Requirements 82
6.3. End Cap Design 83
6.3.1. Vertebral Body Attachment Component 83
6.3.2. Load Application/Positioning Unit 88
6.4. Testing End Cap Purchase 88
6.5. Discussion of End Cap Test Results 93

Chapter 7. Testing the System 94
7.1. Fracture Creation 96
7.2. Initial Compression Bending Test (cycles 1 to 9) 98
7.3. Axial Compression Test (cycles 10 to 16) 104
7.4. Torsion Test (cycles 17 to 24) 106
7.5. Final Compression Bending Test (cycles 25 to 28) 109
7.6. Summary 109

Chapter 8. Conclusions and Recommendations 112
8.1. Improvement of Experimental Methods and Equipment 112
8.2. What is a "Physiological Experiment" ? 113
8.3. Experimental Control of Load and Fracture Site Displacement 114
8.4. Comparing Three, Five and Seven Segment Studies 115
8.5. Other Fracture Types and Instrumentation 115
8.6. Other Applications 116

REFERENCES 117

APPENDIX A. GLOSSARY OF MEDICAL TERMS 128

APPENDIX B. TRANSDUCER DIMENSIONING 130

LIST OF TABLES

TABLE 4.1. SUMMARY OF SPECIMEN MORPHOLOGY FOR TYPE ONE FRACTURE . 45

TABLE 4.2. SUMMARY OF TYPE ONE SPECIMEN FRACTURE LOADS AND DISPLACEMENTS 45

TABLE 4.3. SUMMARY OF VERTEBRA MORPHOLOGY FOR TYPE TWO FRACTURE TEST 47

TABLE 4.4. SUMMARY OF TYPE TWO FRACTURE LOADS AND DISPLACEMENTS . 47

TABLE 4.5. SUMMARY OF MULTIPLE VERTEBRA FRACTURE TESTING (Type Three) 50

TABLE 5.1. TRANSDUCER MATERIAL SPECIFICATIONS 65

TABLE 5.2. TRANSDUCER CALIBRATION AND SPECIFICATIONS 65

TABLE 7.1. TEST OF EXPERIMENTAL METHOD 95

LIST OF FIGURES

FIGURE 3.1. PORCINE SPECIMEN STORAGE AND ALIGNMENT PRESS 17

FIGURE 3.2. HUMAN AND PORCINE SPINES 19

FIGURE 3.3. VERTEBRAL LIGAMENTS 21

FIGURE 3.4. TYPICAL HUMAN LUMBAR VERTEBRA 23

FIGURE 3.5. HUMAN AND PORCINE LUMBAR VERTEBRAE 24

FIGURE 3.6. HUMAN AND PORCINE LUMBAR VERTEBRAE 25

FIGURE 4.1. DEFECT IN LUMBAR VERTEBRA USED FOR FRACTURE TYPE ONE . 30

FIGURE 4.2. DRILL GUIDE TO LOCATE APEX OF WEDGE DEFECT 31

FIGURE 4.3. SAW CUT JIG USED TO REMOVE WEDGE DEFECT FROM VERTEBRA . 32

FIGURE 4.4. LOADING END CAPS FOR FRACTURE CREATION 34

FIGURE 4.5. FRACTURE CREATION SETUP SHOWING DISPLACEMENT TRANSDUCER 34

FIGURE 4.6. DEFECT USED TO PRODUCE FRACTURE TYPE TWO 35

FIGURE 4.7. RESULTANT FRACTURE SURFACE AREA FOR FRACTURE TYPES TWO AND THREE 38

FIGURE 4.8. WEDGE DEFECT INTRODUCED IN THREE VERTEBRA SPECIMEN . . 39

FIGURE 4.9. FRACTURE THROUGH POSTERIOR ELEMENTS OF VERTEBRA SPECIMEN 39

FIGURE 4.10. EFFECT OF DEFECT APEX POSITION RELATIVE TO INFERIOR VERTEBRAL NOTCH ON FRACTURE LOAD 40

FIGURE 4.11. TYPE ONE FRACTURE MODES 42

FIGURE 4.12. TYPICAL LOAD RESISTANCE OF TWO TIMBER TYPE FRACTURES . 43

FIGURE 4.13. FRACTURE SITE DISPLACEMENT OF TWO TIMBER FRACTURES . . 43

FIGURE 4.14. LOAD RESISTANCE OF TWO SPLIT TYPE FRACTURE 44

FIGURE 4.15. FRACTURE SITE DISPLACEMENT OF TWO TYPICAL SPLIT FRACTURES 44

FIGURE 4.16. REPEATIBILITY OF VERTEBRA RESISTANCE TO LOAD FOR FRACTURE TYPE TWO 48

FIGURE 4.17. REPEATIBILITY OF TYPE TWO FRACTURE DISPLACEMENT 48

FIGURE 4.18. TYPE THREE FRACTURE LOADING OF SEVEN SEGMENT SPINES . . 49

FIGURE 4.19. VERTICAL FRACTURE DISPLACEMENT (type three) OF SEVEN SEGMENT SPINES 49

FIGURE 4.20. ACOUSTIC EMISSION RESPONSE SHOWING TWO SIGNIFICANT FRACTURES DURING FRACTURE CREATION 50

FIGURE 5.1. PREVIOUS GLOBAL MEASUREMENT TECHNIQUE SHOWING SPINE AND MARKER RINGS 57

FIGURE 5.2. MARKER RING AND CAMERA ORIENTATION FOR PREVIOUS GLOBAL MEASUREMENT TECHNIQUE 57

FIGURE 5.3. PHOTOGRAPHIC/CROSS-HAIR TECHNIQUE TO RECORD LOCAL FRACTURE SITE MOTION 60

FIGURE 5.4. BIAXIAL TRANSDUCER MOUNTED ON PORCINE VERTEBRA WITH WEDGE DEFECT 62

FIGURE 5.5. TRANSDUCER DETAILS 64

FIGURE 5.6. UNIAXIAL ERROR IN Z DIRECTION 67

FIGURE 5.7. X DIRECTION ERROR DURING Z DISPLACEMENT 67

FIGURE 5.8. UNIAXIAL ERROR IN X DIRECTION 69

FIGURE 5.9. Z DIRECTION ERROR DURING X DISPLACEMENT 69

FIGURE 5.10. INSTALLATION OF GLOBAL AND LOCAL MEASUREMENT SYSTEMS . 71

FIGURE 5.11. COMPRESSION TEST GLOBAL PHOTOGRAPHIC/DIGITIZED VERTICAL (z) DISPLACEMENT RESULTS AT CENTRE OF MARKER RINGS . . 73

FIGURE 5.12. COMPRESSION TEST GLOBAL PHOTOGRAPHIC/DIGITIZED FLEXION ROTATION RESULTS AT CENTRE OF MARKER RINGS 73

FIGURE 5.13. REDUCED GLOBAL PHOTOGRAPHIC/DIGITIZED RESULTS AT ANTERIOR VERTEBRAL BODY FOR COMPRESSION TEST 74

FIGURE 5.14. LOCAL TRANSDUCER MEASUREMENT OF DISPLACEMENT IN FRONTAL PLANE AT ANTERIOR VERTEBRA BODY DURING COMPRESSION TEST 74

FIGURE 5.15. GLOBAL PHOTOGRAPHIC/DIGITIZED VERTICAL DISPLACEMENT DURING ROTATION TEST 75

FIGURE 5.16. GLOBAL PHOTOGRAPHIC/DIGITIZED FLEXION ROTATION DURING ROTATION TEST 75

FIGURE 5.17. LOCAL TRANSDUCER MEASUREMENT RESULTS OF ROTATION TEST . 76

FIGURE 5.18. THREE TRANSDUCER SYSTEM FOR THREE DIMENSIONAL MEASUREMENT 78

FIGURE 6.1. ENDCAP AND COMPRESSION LOADING FIXTURE 84

FIGURE 6.2. END CAP MOUNTING DETAIL 85

FIGURE 6.3. OVERVIEW OF END CAP 87

FIGURE 6.4. ATTACHMENT OF DISPLACEMENT TRANSDUCER TO END CAP . . . 87

FIGURE 6.5. DISPLACEMENT OF VERTEBRA RELATIVE TO END CAP DURING A COMPRESSION TEST 90

FIGURE 6.6. EFFECT OF REPETITIVE COMPRESSION LOADING ON RELATIVE END CAP MOVEMENT 90

FIGURE 6.7. DISPLACEMENT OF VERTEBRA RELATIVE TO END CAP DURING A TORSION TEST (CYCLE 1) 91

FIGURE 6.8. DISPLACEMENT OF VERTEBRA RELATIVE TO END CAP DURING A TORSION TEST (CYCLES 1 - 5) 91

FIGURE 6.9. EFFECT OF TORSIONAL OVERLOAD ON END CAP PURCHASE . . . 92

FIGURE 7.1. COMPRESSION LOADING DURING FRACTURE CREATION 97

FIGURE 7.2. VERTEBRAL DISPLACEMENT DURING FRACTURE CREATION 97

FIGURE 7.3. COMPRESSION BENDING TEST MOMENT ARMS 99

FIGURE 7.4. CYCLE 1 LOADING 100

FIGURE 7.5. CYCLE 1 VERTICAL FRACTURE DISPLACEMENT 100

FIGURE 7.6. LOADING FOR CYCLES 2, 3 AND 4 101

FIGURE 7.7. VERTICAL FRACTURE DISPLACEMENT FOR CYCLES 1,2,3 AND 4 . 101

FIGURE 7.8. COMPRESSION BENDING TEST LOADING (CYCLES 5 - 9) 103

FIGURE 7.9. COMPRESSION BENDING TEST FRACTURE DISPLACEMENT (CYCLES 5 - 9) 103

FIGURE 7.10. COMPRESSION TEST LOADING (CYCLES 10 - 16) 105

FIGURE 7.11. COMPRESSION TEST FRACTURE DISPLACEMENT (CYCLES 10 - 16) 105

FIGURE 7.12. TORSION TEST LOADING (CYCLES 20 - 24) 107

FIGURE 7.13. TORSION TEST FRACTURE DISPLACEMENT (CYCLE 20) 107

FIGURE 7.14. TORSION TEST LATERAL DISPLACEMENT (CYCLES 20 - 24) . . 108

FIGURE 7.15. COMPRESSION BEND TEST LOADING (CYCLES 5,25,26,28) . . . 108

FIGURE 7.16. COMPRESSION BEND TEST FRACTURE DISPLACEMENT (CYCLES 5,25,26,28) 110

FIGURE B.1. TRANSDUCER MOMENT ARM DETAILS 131

Chapter 1. Introduction

Loss of structural integrity of the spinal column and neurological damage often results from a fractured vertebra. The surgeon must reduce and support the vertebra to prevent further neurological damage and to ensure healing. Frequent failure of external bracing has prompted the use of internal implants. An anterior approach through the abdominal cavity and a posterior approach are the two most common modes of surgical implantation. This study addresses posterior fracture reduction which requires a fixation device to resist eccentric loading significantly posterior to the normal loading centroid through the vertebral body. Loads due to body weight and muscle forces must bridge the fracture site through a fixation device interfacing with bone not intended to carry such loading.

Inherent design problems of many fixation devices and improper surgical application have resulted in catastrophic failure. Inadequacies with existing posterior fixation devices are loosening and pullout of screws and hooks, implant and bone breakage, bending and plastic deformation, ineffective fracture reduction, adjustability and difficulty of installation and an inability to protect the fracture under normal (physiological) loads.

This thesis addresses only the ability of a fixation device to prevent motion at the fracture site. The experimental system may be used to quantify other problems, but regardless of the cause, protection of the fracture is the first requirement of a fixation system. Lack of spinal fusion is related to the inability of a fixation device to prevent motion at the fracture site although being fully capable of

support.

Testing spinal fixation instrumentation to determine its effectiveness is usually performed "in vitro". Instrumentation (fixation device) is attached to an animal or human spine on which a simulated fracture has been created. The spine is loaded and measurements are made to determine motion globally or locally. Because of discs, connecting ligaments and other soft tissues, the test specimen may exhibit gross flexibility, resulting in poor experimental control.

Experimenters acknowledge significant differences between "in vitro" and "in vivo" behaviour of instrumented spines. Support is provided by paraspinal muscle activity, the rib cage and other abdominal structures. Ideally, fracture site remodelling and healing that occur "in vivo" improve the structural integrity of the spine with time, whereas tissue deterioration is more likely to occur "in vitro". Nevertheless, "in vitro" testing of spinal fixation devices is the only large scale basis for evaluation. Performed with rigorous experimental care, these results provide considerable useful information.

The purpose of this investigation was to establish an in vitro experimental method to reliably and accurately evaluate the effectiveness and performance of posterior internal spinal fixation devices. An accurate experimental model will provide surgeons with an understanding of the characteristic limitations of individual spinal fixation devices. It may also be used to help determine the engineering and design requirements for optimization of an internal fixation device which would provide maximum stabilization of a fractured, clinically unstable spine. The call for an accurate experimental technique is prompted by the increasing number of spinal fixation devices being

developed and marketed for the surgical management of vertebra fractures and the need for an accurate objective evaluation of the effectiveness of each device in stabilizing particular types of fractures.

The initial intent of the study was to evaluate the existing experimental method and techniques used by Moreau, Budney, Raso, et al at the University of Alberta and improve upon shortcomings in order to produce satisfactory experimental results related to the effectiveness of various spinal fixation devices. However, consideration of the experimental problems within the existing method led to broadening of the scope of this study. Analysis of discrete experimental components (ie. measurement, end conditions, loading, data analysis, fracture creation) resulted in a total redesign of the techniques and apparatus for the entire experiment including the fundamental basis for quantifying the efficacy of spinal instrumentation.

Chapter 2. Historical Review

2.1. Biomechanical Studies of the Intact Human Spine

Early engineering studies and evaluations of the mechanical and material properties of the human vertebral column were initiated to better understand the mechanism of spinal injury experienced by pilots during ejection from high speed aircraft. Initial ejection seat studies using humans during World War II are described by Glaister (1965) and Watts (1947).

Early breaking strength tests of cadaveric vertebral components subjected to uniaxial compression were done by Ruff (1940) followed by load-deformation studies by Virgin (1951), Perey (1957), Brown (1957) and Evans (1959). Hirsh (1955) performed the first dynamic (vibration) tests. Roaf (1960) characterized the mechanics of spinal injuries and hypothesized that almost every type of spinal injury could be produced with a combination of compressive and rotational loading. Nachemson (1959) introduced a method for measuring intradiscal pressure using a transducer which penetrated the nucleous pulposus and published results of testing on living humans and cadavers (1966) subjected to various loading regimes. Rolander (1961) preloaded specimens during testing and examined the mechanics and properties of lumbar motion segments subjected to simulated fusion (1966). The effects of strain rate under axial compression was first addressed by Crocker and Higgins (1966). Markolf (1969) presented further results on the mechanical behavior and stiffness of the vertebral spinal column. Vulcan and King (1971) performed elastic deformation studies using strain gauges mounted on individual vertebra of intact cadavers subjected to eccentric spinal

impact loading. They postulated that bending was a significant factor in vertebral fractures. Kazarian (1972) studied the effects of preload on dynamic properties of the spine. Panjabi (1976) addressed the importance of low physiological loading of in-vitro specimens to ensure permanent damage to the motion segment was avoided and recommended relaxation intervals between load applications to eliminate the effects of creep on experimental reproducibility. Panjabi concluded coupled motion was characteristic of vertebral joints. Panjabi (1977) also studied the effects of preload on load displacement curves. Lin (1978) examined the load bearing function of the articular processes during complex physiological (combined compression and bending) loading of the intervertebral joint and applied what he felt was an in-vivo compression bending load of 1300 N, 10 mm anterior to the center of the vertebral body resulting in a 13 Nm bending moment assuming the center of the body acted as a fulcrum. Berkson, Nachemson and Schultz (1979) published results on the influence of age, sex, disc level and degree of generation on the mechanical behavior of lumbar motion segments. They found that 10.6 Nm was required to emulate an in vivo flexion rotation of 5.5 degrees in an intact specimen and demonstrated the relevance and importance of preloading in-vitro specimens during experimental loading. Tencer (1981) conducted similar tests on unconstrained vertebral joints and showed that "the intervertebral joint is highly sensitive to position of the compression force line of action and has a mechanical balance point slightly posterior to the center of the disk." Posner et al. (1982) studied the motion of lumbar and lumbarsacral spinal segments under simulated physiologic flexion and extension movement. Cadaveric specimens were subjected to initial

preloads and maximum loads based on Nachemson's data and time interval for creep as suggested by Panjabi et al. Elements of the specimens were sequentially transected until failure occurred. Goel et al. (1985) performed kinematic studies on lumbar cadaver spinal segments with various surgically created injuries and determined the respective clinical instability. Three dimensional motion was recorded using an optoelectronic (Selspot) motion analysis system with fully automated processing.

Many kinematic motion studies of the spine in living humans have been done. Two examples are Greyersen and Lucas (1967) and Pennal et al (1972) using mechanical and radiographic techniques respectively. Biomechanical definitions of clinical stability of intact spines have been stated by White and Panjabi (1978) and Pope and Panjabi (1983).

2.2. Fracture Instability Criterion

Recent surgical management techniques of the fractured thoracic and lumbar spine have been described by a number of authors including McAfee et al. (1982), Dewald (1984), Gaines and Humphreys (1984), Jacobs and Casey (1984), Lifeso et al. (1985) and Bolman (1985). They catagorized fracture types and recommended appropriate measures of treatment and fixation. Holdsworth [167] described a two column stability theorem and stated that disruption of the posterior ligamentus complex (posterior column) was sufficient to create spinal instability. Nagel [36] showed that additional partial disruption of the annulus fibrosus and posterior longitudinal ligament was required. As well, recent classification and definition of clinical spinal instability has been addressed by Frymoyer and Selby (1985) who clas-

sified rotational, translational and various other instabilities. Recently Denis (1983) put forth a three column theory (anterior, middle and posterior columns) defining and classifying clinical instability with respect to fracture type. The anterior column consists of the anterior body and anterior annulus fibrous with the middle column comprised of the posterior vertebral body wall, the posterior longitudinal ligament and posterior annulus fibrosus. The posterior column consists of the posterior bony and ligaments complex. Denis described four major types of spinal injuries and failure modes of the three columns. The compression fracture is described as a failure of the anterior column in compression and a possible distraction failure of the posterior column in severe cases (with no failure of the middle column). The burst fracture has a compression failure of the anterior and middle columns and no disruption of the posterior columns. Seat belt type injuries fail in distraction in the middle and posterior columns with no failure of the anterior column which acts as a hinge. In fracture dislocations the anterior column fails in compression, rotation and/or shear with the middle and posterior columns failing in distraction, rotation and/or shear. He also described three degrees of instability. The first degree of mechanical instability occurs when the "spinal beam" buckles or angulates and is representative of severe compression fractures or seat belt injuries. Second degree is a neurologic instability associated primarily with burst fractures as vertical collapse may retropulse bone into the spinal canal. Third degree instability is both mechanical and neurological and represented by fracture dislocations and unstable burst fractures.

Identification of fracture characteristics has helped the surgeon

determine the proper mode of treatment but not the most effective fixation device. Experimental modelling of a fracture must also conform to relevant in vivo failure modes.

2.3. Development of Posterior Spinal Fixation Devices

1910 was perhaps the earliest known application of internal spinal fixation when Professor Fritz Lange attached tin-coated steel bars to spinous processes using braided silk. King (1944), Boucher (1959), Thompson (1949), and Pennal (1964) used screws to immobilize fractured vertebrae. Wilson (1952), Holdsworth (1963) and Williams (1963) described the attachment of plates to the spinous process as an aid to spinal fusion. Harrington (1962) was the first to develop rods for scoliosis treatment. Kaufer (1966) introduced spinous process wiring to reduce and immobilize the fracture site. Dickson (1973) and Flesh (1977) described the use of Harrington rods for reduction of fractures and fracture dislocations and Weiss (1975) introduced springs for dynamic stabilization of the spine. Luque (1982) developed a smooth rod with segmented wiring and incorporated pedicle screws in 1986 for fracture fixation applications. Other notable fixation devices incorporating pedicle screws introduced by Boucher were described by Roy-Camille (1970), Herrmann (1979), Cotrel and Dubousset (1984) and Steffee (1986). A multitude of other posterior fixation devices with numerous modifications to the long rod and pedicle screw techniques have followed.

Comparison of conservative versus operative treatment was described by Lewis (1974) and found the operative group was more successful. Other studies of compresssion fractures of the thoracolumbar spine by

Soreff (1977) and Dorr et al. (1982) found the conservative treatment was vulnerable to flexion type deformations and felt that internal fixation would enhance recovery of spinal injuries. Jacobs (1980) and other orthopaedic surgeons following the performance of their internal fixation applications indicated that benefits of internal fixation outweighed the risks. There has been increasing acceptance that reduction of an unstable spine by internal fixation enhanced patient mobilization and recovery. This has generated the development and implementation of a variety of fixation instrumentation. However, in 1978 Dickson published results showing relatively high complication rates using Harrington rods. Post-operative failures of fixation devices due to inherent design deficiencies as well as poor operative management prompted the need for rigid biomechanical evaluation and testing and thorough categorization of fracture types, respective stabilities and recommended fixation application.

2.4. Biomechanical Testing of Posterior Spinal Fixation Devices

Numerous investigators have published results of in vitro testing of spinal instrumentation although many offer only incomplete descriptions of experimental methods and materials. The more significant and explicit contributions to in-vitro spinal implant testing is reviewed.

Stauffer and Neil (1975) tested three methods of internal fixation with regards to strength, mechanical integrity, failure mode and technical ease of application when applied to surgically simulated thoracolumbar spinal flexion-rotation fractures. Instrumented cadaveric spinal segments were loaded in complex flexion-rotation to failure and compared. Dunn et al. (1979) compared two posterior devices and

one anterior device on cadaveric spines with simulated injuries at T12 loaded in pure rotation about the spinal axis over a 360 degree range. Pinzur et al. (1979) examined load deformation characteristics of three posterior devices implanted on cadaver spines and loaded in four point bending (flexion). Laborde et al. (1980) mechanically introduced flexion, extension and lateral bending failures at the thoracolumbar junction of fresh and embalmed cadaver spines using three point bending. Comparison of three methods of posterior fixation was accomplished through four point bending of the instrumented spines loaded at a rate that produced failure between three and fifteen seconds. He also showed significant differences between fresh and embalmed cadaver results. Nagel et al. (1981) subjected five complete human cadavers to a range of motion and measured movement with displacement transducers between L1 and L2 vertebra levels as progressive incisions were introduced in the posterior elements until a clinically unstable condition was created. Three external braces and two methods of posterior internal fixation were compared. Although he was first to accurately measure motion at a surgically simulated spinal injury subjected to relevant in vivo motion (similar to in vivo radiographic methods) he was criticized for lack of force measurement. Purcell et al. (1981) sectioned posterior ligaments at the L1 - T12 level in cadaver spines and loaded the spines in compression bending to failure resulting in disruption at the L1 - T12 disc space. He compared different levels of fracture fixation by loading the instrumented spines to failure. Injury site displacement was measured with an extensometer located at the pedicles of L1 and T12 vertebrae. Jacobs et al. (1982) simulated anterior, posterior and combined injuries of

both the posterior ligament and anterior bone in cadaveric spines. Fixation instrumentation appropriate to the type of fracture introduced was implanted and subjected to four point bending to failure with specimen angulation measured at the T12 vertebra. Calf spines were used in-vitro by Wenger et al. (1982) to examine various long rod fixation techniques for scoliosis application. The specimens were subjected to longitudinal compressive, rotation and forward bending loads to failure. Goel and Panjabi et al. (1983) claimed physiological loading ensured specimen degradation was minimized and enabled multiple or repetetive testing of a cadaveric spine by employing creep and relaxation allowances. They performed a comprehensive analysis of "physiologic three dimensional motion behaviour of normal, injured and stabilized spine specimens subjected to various load types." Three sequentially simulated injuries (similar to Purcell et al.) were introduced into cadaver spines and subjected to physiological flexion, extension, lateral bending and torsional loads. Resulting three-dimensional motion was recorded using stereo - photogrammetry techniques. Haher et al. (1983) and Kostiuk et al. (1983) presented results of cyclic loading tests of instrumented spinal segments. Kostiuk et al. simulated burst fractures in bovine spines and compared various anterior and posterior devices subjected to loading cycles. Measurement of three-dimensional motion of the spine was achieved using a wire/potentiometer apparatus. Haher et al. evaluated human cadaver spines with Luque instrumentation subjected to 140,000 load cycles at twenty-five cycles per minute. McCarthy et al. (1983) subjected instrumented dog spines to failure. Johnston et al. (1983) tested various instrumentation for scoliosis applications using Holstein calf

spines subjected to three point bending loads to failure. Moreau et al. (1983) utilized porcine spines for evaluation of various posterior fixation devices. Fractures were introduced by simulating a wedge defect in the anterior body and applying longitudinal compression loads to failure. The porcine specimens were subjected to sub-failure compression, compression bending and torsion loads. Three dimensional analysis of motion was provided using a photographic/digitizing technique that quantified movement of individual vertebra. McNiece (1983) removed the T12 vertebra body in cadaveric specimens to emulate a burst fracture and compared posterior instrumentation devices subjected to axial and torsional loading. Fracture site motion was determined using a thumb tack/photographic technique. Weiler (1983) described a plastic spinal model in his dissertation for testing spinal fixation devices in scoliosis treatment. McAfee et al. (1984) used both fresh and embalmed human cadaver spines for testing posterior fixation devices. Three types of fractures were simulated in the specimens which were subjected to an axial preload followed by axial compression and rotation loading to failure. Munson et al. (1984) described testing of Harrington rods using calf spines with a two cm segment removed from the L1 vertebra subjected to axial compression, lateral bending and rotation loading. Deflections were measured using a "strain clip" spanning the simulated vertebral defect. Nasca (1985) subjected mature swine spines instrumented with posterior fixation for treatment of scoliosis to cyclic axial compression loading. Spinal motion was photographically recorded at various intervals over the 10,000 cycle loading regime. Gaines et al. (1986) describes the use of calf spines with simulated transverse slice fractures as a model for

evaluating fixation devices. Physiological loading (5 foot-pounds) was applied and spinal movement monitored using a three-dimensional travelling microscope system. Bovine spine and mechanical geometric spine simulation apparatus which induced various loading regimes were developed by Hoeltzel (1986) for evaluation of spinal instrumentation. Geometric simulation provides a means of evaluating posterior fixation devices independent of human or animal in-vitro specimens. Fidler (1986) compared techniques of posterior instrumentation using a mechanical model based on imitation polyester vertebrae. Gepstein et al. (1986) emulated burst fractures in human cadaver spines for comparison of various fixation devices subjected to axial and flexion loading to failure.

2.5. Problems with Experiments

A comparison of spinal fixation experiments reveals modelling discrepencies and gross variations within experimental protocol. This is due to the extreme difficulty in modelling the internally fixated human in-vivo fracture subjected to normal daily patient activity. A detailed review of previous experimental difficulties is addressed later in this thesis. In general, lack of uniform specimens, poor specimen handling and preparation, poor fracture model reproducibility or an inappropriate fracture model, improper end conditions and loading, an unsound basis for evaluation and measurement inaccuracies all contribute to inconclusive results. There are many other modelling considerations that are virtually impossible to emulate such as in vivo trunk stiffness, abdominal pressure and in vivo regenerative capacities. Further, the basis for evaluating a fixation device is not common

among the different investigators. The object of this thesis is to develop a sound testing protocol which removes the significant variables and provides an accurate, objective means of evaluating the effectiveness of posterior spinal fixation devices.

Chapter 3. Spinal Model

Many researchers [62, 66, 83, 84, 68, 78, 69, 85, 86, 58, 87, 89, 22, 8, 76, 70, 12, 13] performed in vitro experiments using excised human cadaver spines, but lack of availability of a uniform sample of cadaver spines left many experiments unsound due to extreme variations in age, size and condition of specimens. Significant biomechanical and biological differences have been reported between fresh and embalmed spines [7, 22] making comparisons difficult. Because clinicians do not accept model spines constructed of homogeneous, isotropic materials [88], the experimenter is left with the choice of in vivo or in vitro animal models. Living animal models have the desired regenerative capabilities and musculature but they are all quadrupeds. Animal spines, used to model human spines in numerous in vitro experiments, feature geometrical and functional discrepencies. Bovine (calf) spines used by some researchers [74, 69, 90, 92, 93, 94, 95, 96, 82, 81] are criticized for cartilagenous vertebral body growth plates which are sensitive to shear stresses [80, 97]. Mature porcine (sow) spines have been used in numerous studies [98, 99, 100, 80, 101] due to the availability of large, uniform populations at low cost. Aside from differences in proportions, mature porcine (sow) spines reasonably model human spines as they have similar morphology and do not possess sensitive growth plates.

3.1. Specimen Excision, Handling and Storage

Specimens used for this study were part of a large homogeneous population of uniform sow spines excised from disease free animals of

similar age, size and sex. The sows, used for reproductive studies at the Alberta Agriculture Research station, Lacombe, Alberta, consumed the same feed, received no drugs and were slaughtered at the same age and weight of approximately 2 years and 300 pounds. Meat from the animals was government inspected and sold for human consumption. Complete spines were excised, packaged in double plastic bags and shipped 60 miles to the University of Alberta where they were then placed in frozen storage. Further trimming of the spines was done prior to testing.

Inventory of the sow spines during the study showed many specimens suffered from severe curvature, twisting and deformation due to poor methods of handling, transport and freezing the freshly excised spines. The gross specimen deformation and variation in geometry was conserved after thawing. These specimens could not be used as experimental reproducibility of end conditions and loading would be difficult.

To overcome this problem, methodology was devised to maintain specimen uniformity during transportation, handling and storage. Abbatoir personnel agreed to precisely excise the desired vertebra spinal segment leaving a layer of flesh for protection against dehydration. The fresh, flexible spines were sealed in double plastic bags and placed in specially designed wooden presses to maintain precise alignment (Figure 3.1). A longitudinal groove in one block aligned the spinous processes. The vertebra bodies were aligned by a 120 degree longitudinal V-notch in another block placed on top. Light clamping of the two blocks maintained specimen uniformity and geometry during transportation, handling and freezing. The wooden blocks were removed once the spines were frozen.

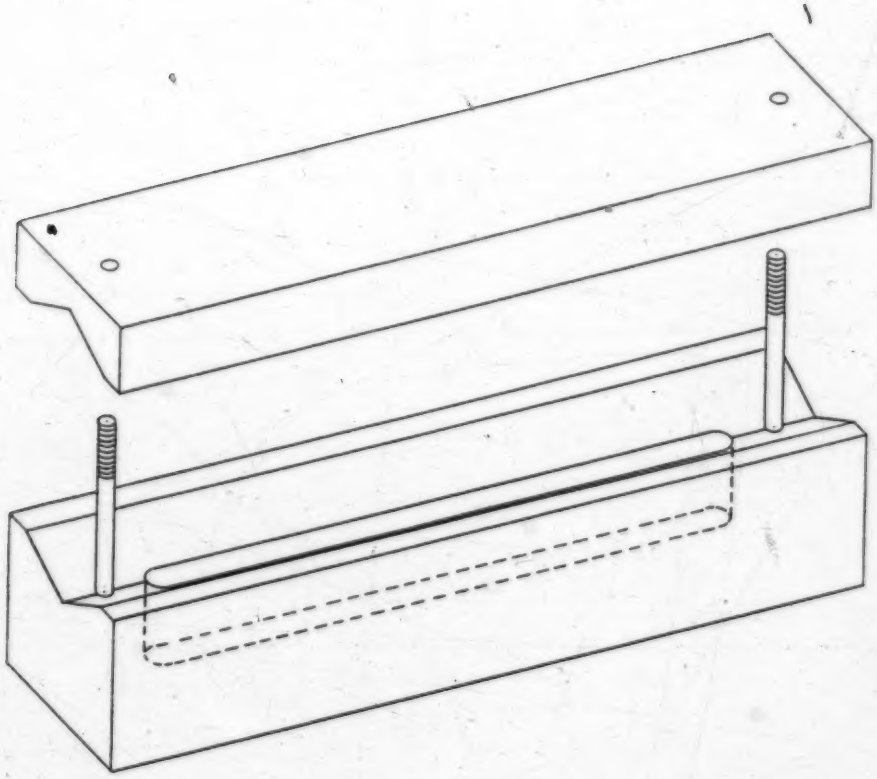


FIGURE 3.1. PORCINE SPECIMEN STORAGE AND ALIGNMENT PRESS

3.2. Anatomical Comparison of Porcine and Human Vertebra

As porcine specimens are used to model human in vivo conditions, a geometrical and physiological comparison of human biped and porcine quadruped spinal structures is fundamental. A side view of human and porcine vertebral columns is shown in Figure 3.2. The human T9 to L5 vertebra segment with a fractured L1 vertebra is the anatomical area of interest in this study. It should be noted that the porcine spine has fifteen thoracic vertebra, however for purposes of this study the T15 porcine vertebra will be designated T12 to remain consistent with human anatomy. The human spine has a thoracic kyphosis and a lumbar lordosis with an inflection point at the T12/L1 level. The same porcine spinal region has only a kyphosis.

For both biped and quadriped, the spine is the primary load bearing structure featuring attachment points for musculature, which provides movement and balance. Both spines allow limited articulation, absorb energy, dampen vibration and provide a protective conduit for the complex network of the spinal nervous system [2]. Although human and porcine spines have similar structural components and perform similiar functions, geometrical disparities are indicative of load carrying differences between biped and quadruped. The human spine is a column like support structure in which each vertebra must resist muscle forces and loading due to body weight superior to it where as the porcine spine is an arch like structure supporting a hanging load and resisting different muscle forces.

Human and porcine spines have similar complex joint structures between vertebrae. Attached to the vertebral bodies are fibrocar-

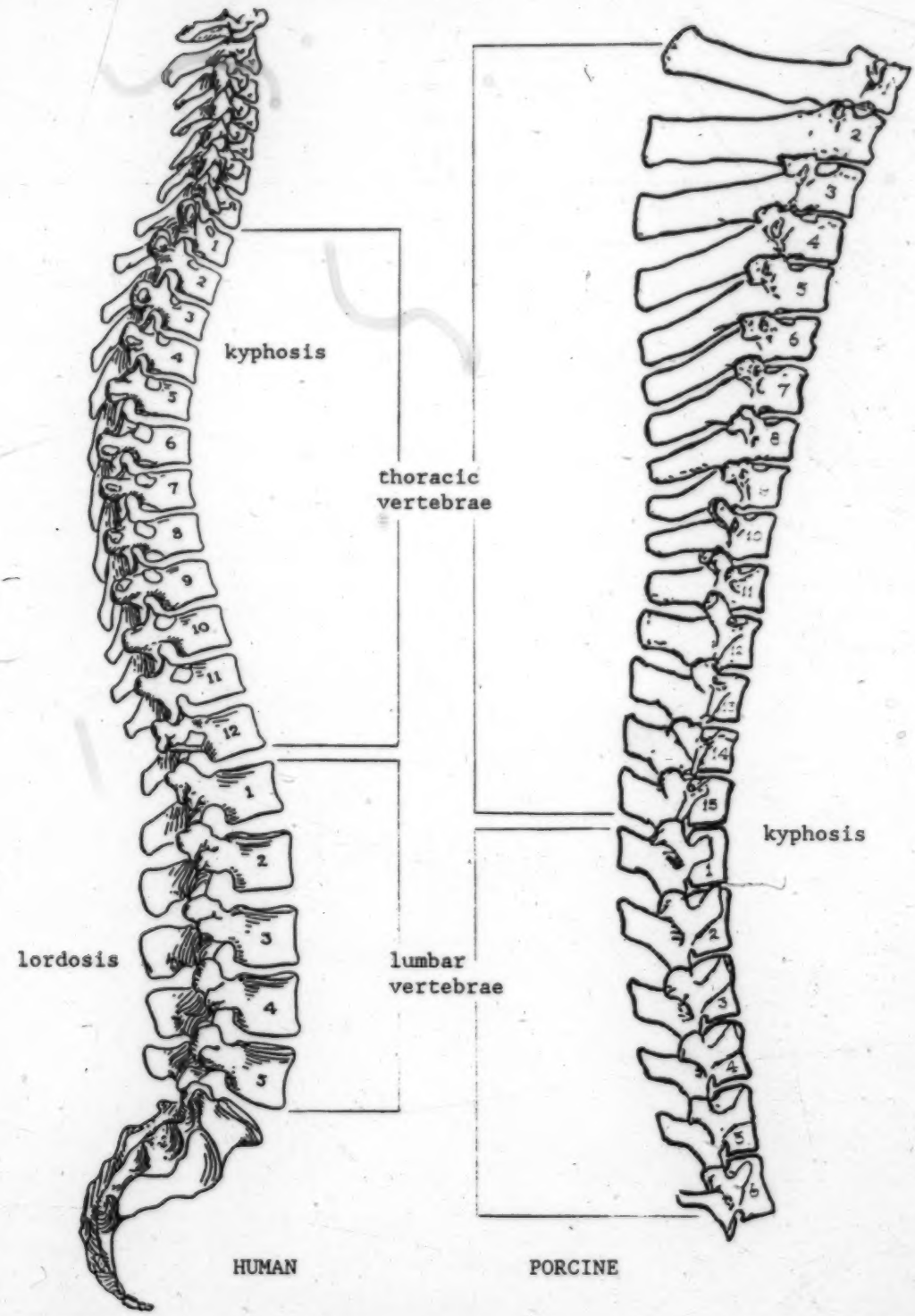


FIGURE 3.2. HUMAN AND PORCINE SPINES
(Modified From References 1 and 3)

tilaginous joints known as symphyses (intravertebral discs) that provide secure, slightly movable junctions containing no lubricating fluid [5]. Vertebrae also articulate on smooth mating surfaces or synovial joints comprising the articular processes (facet joints). A synovial joint allows free, low friction movement with the junction confined by external ligaments and filled with a lubricant called synovial fluid. Figure 3.3 shows a longitudinal network of connecting ligaments which link the vertebrae into a mechanical structure. A ligament's primary function is to provide flexible yet restricted movement and to absorb energy. The strong fibrous anterior longitudinal ligament spans the entire length of the spinal column and attaches to the anterior of each vertebral body and intravertebral disc. A thinner posterior longitudinal ligament attaches to superior and inferior margins of adjacent vertebral bodies. The ligamentum flavum joins adjacent vertebral arches. The intraspinous ligament joins adjacent spinous processes along their extensions. Tips of the spinous processes are tied together with the strong supraspinous ligament which travels the length of the spine. It should be noted that the number and relative positions of ligaments are essentially identical for both models.

A complex muscle system is attached to the transverse and spinous processes on both human and porcine spines and is responsible for motion of the spinal column. Groups of muscles accomplish physiologic translations and rotations which combine to provide complex intervertebral joint motion.

Both human and porcine vertebra comprise a vertebral body, a spinal canal, facet joints and process structures that have relatively the

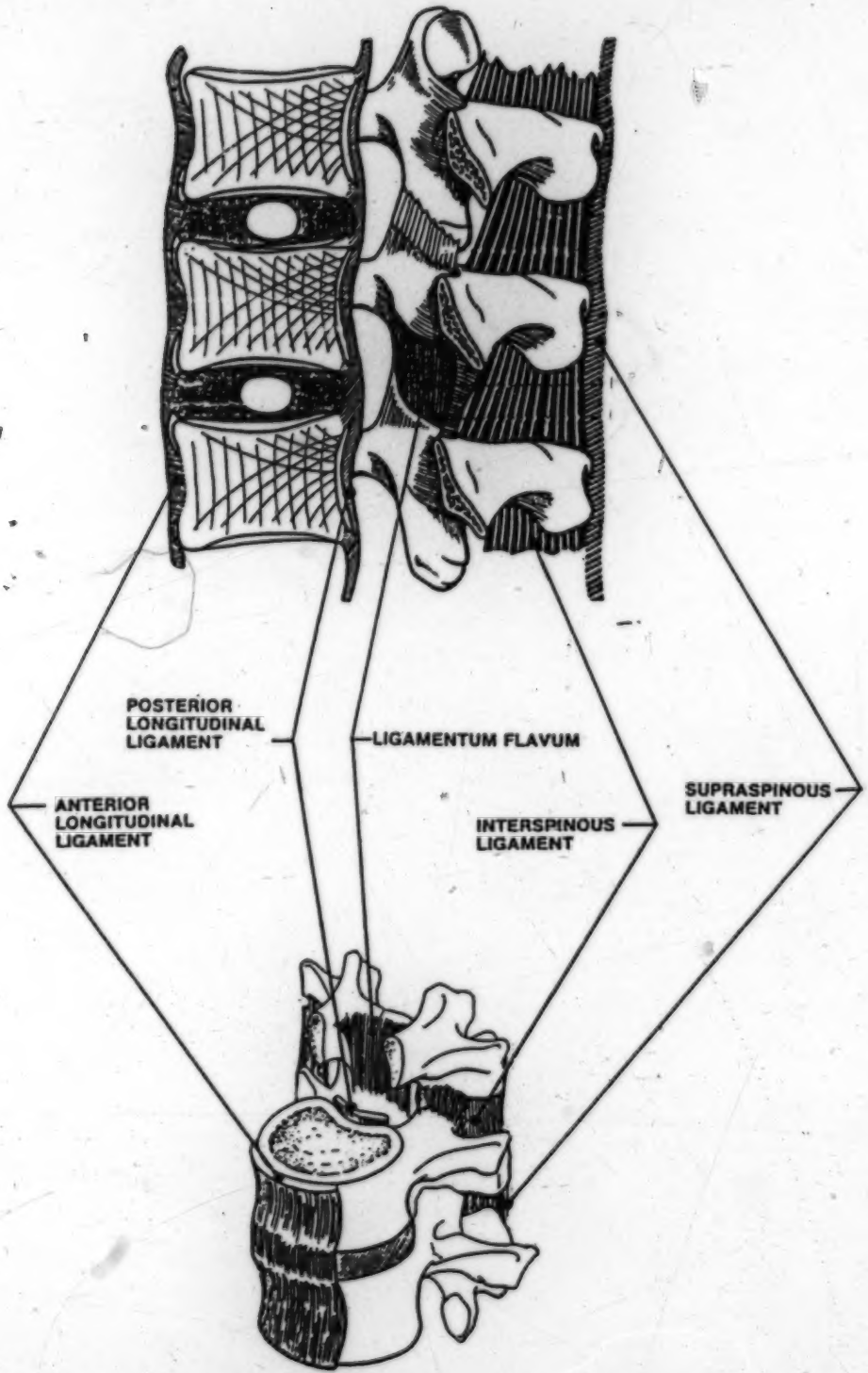
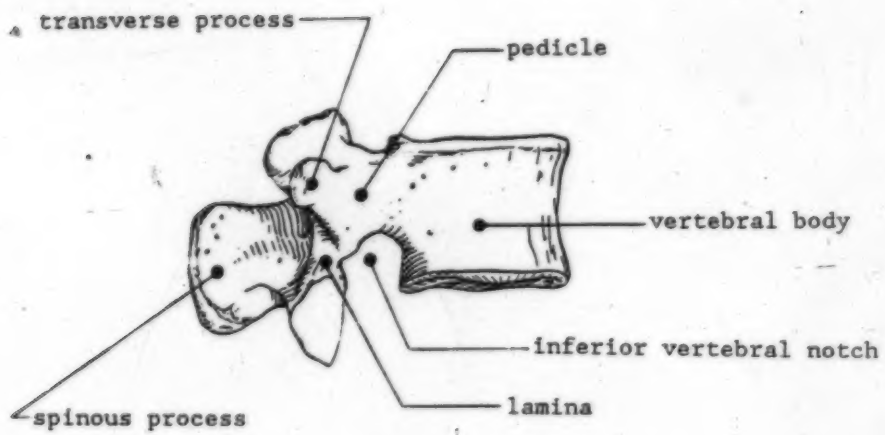


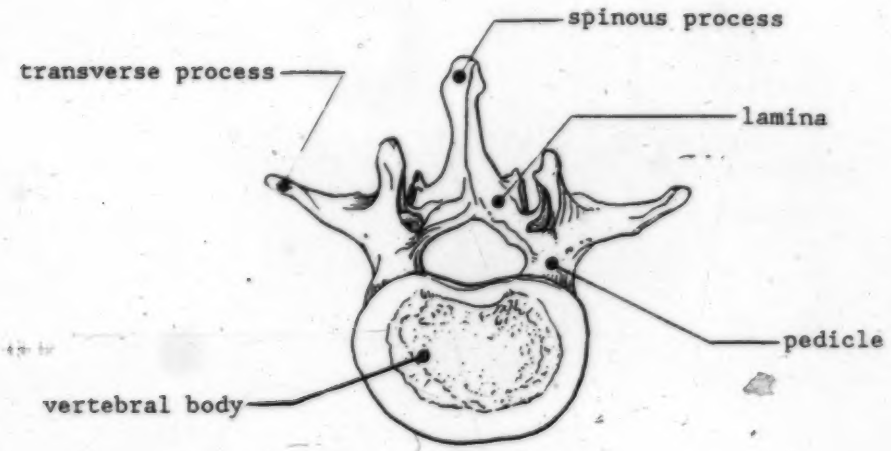
FIGURE 3.3. VERTEBRAL LIGAMENTS
(Modified From References 4 and 27)

same orientation and position. Figure 3.4 shows typical full scale human L2 lumbar vertebra [1] and its components. Superior and lateral views of comparatively scaled human and porcine lumbar vertebra are shown in Figure 3.5. The vertebrae are overlayed in Figure 3.6 with respective longitudinal centerlines and mid-body heights fixed. Vertebral loading characteristics explain discrepencies in size and proportion between respective human and porcine components. The smaller load bearing area of the porcine vertebra body and more substantial posterior elements are consistent with the loading regime of the arch structure. The top view shows similar spinal canal (vertebra foramen) cross sectional areas with the porcine being slightly more elongated laterally. A/P body length for porcine and human was 26.5 mm and 31 mm respectively (15 percent difference). Body width (transverse) was 40 mm and 44.3 mm (10 percent difference) and cross-sectional vertebral body area was 818 mm2 and 1188 mm2 (31 percent difference) for porcine and human respectively. Body height was 28 mm for the human and 42 mm for porcine (33 percent difference). Pedicle height is 28 mm for the porcine and 15 mm for human (87 percent difference). Human pedicle width was 9 mm compared to porcine pedicle width of 10 mm (11 percent larger).

The porcine transverse process is located approximately 7 to 8 mm more anterior than the human. The lateral centerline of the transverse process is approximately perpendicular to the longitudinal axis of the spinal canal. Angular orientation of the human transverse process is approximately 15 degrees more anterior. The shorter human transverse processes are modelled by trimming the more massive porcine transverse processes to match the facet joint width. The maximum distance between

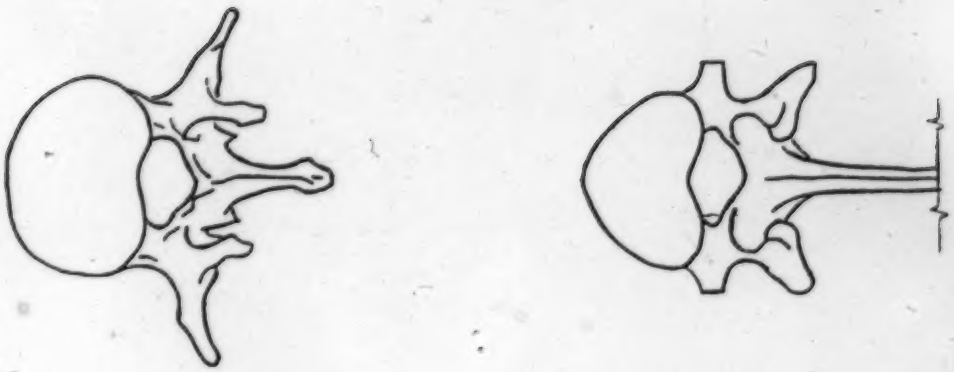


SIDE VIEW



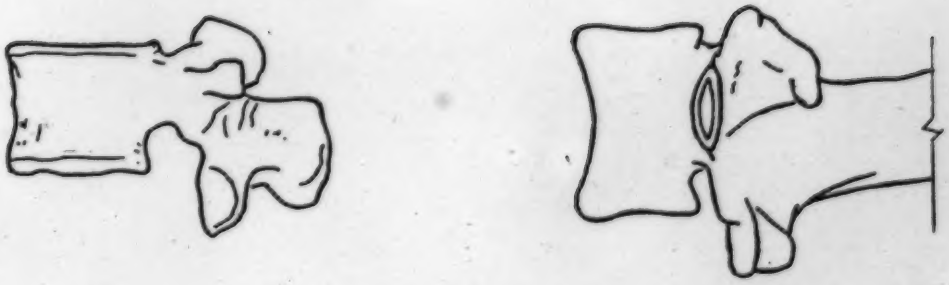
TOP VIEW

FIGURE 3.4. TYPICAL HUMAN LUMBAR VERTEBRA
(Modified From Reference 1)



TOP VIEW

HUMAN [1] PORCINE



SIDE VIEW

FIGURE 3.5. HUMAN AND PORCINE LUMBAR VERTEBRAE
(Modified From Reference 1)

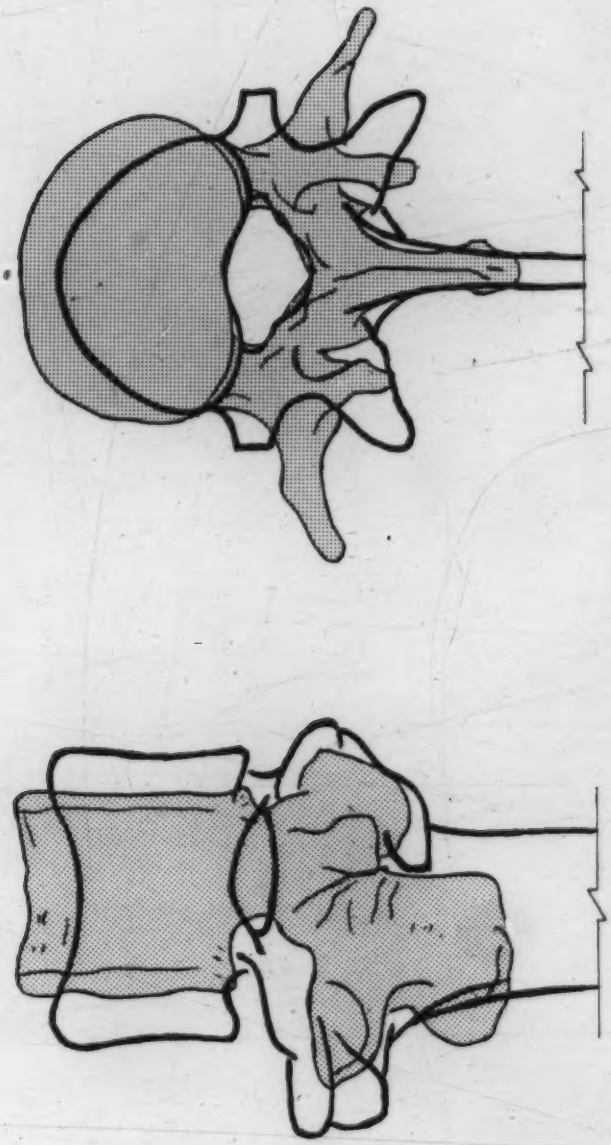


FIGURE 3.6. HUMAN AND PORCINE LUMBAR VERTEBRAE (overlay)
(Modified From Reference 1)

the tips of the inferior and superior articular processes (facet joint) is 62 mm and 50 mm for the porcine and human respectively. The location of the facets differ slightly, with porcine slightly more anterior than human. The porcine facet has a semi-cylindrical/socket progressing anteriorly to a flat surface similar to the human facet which is entirely planar. The cylindrical/socket allows flexion but extension and anteroposterior translation is severely limited providing greater resistance to shear loading than human facet joints. The flat extension provides additional resistance to torsional loading with respect to the longitudinal axis. The lamina connecting the articular processes is more massive in the porcine than human indicating greater loading in the posterior elements (especially in shear). The spinous process is much larger in the porcine than in the human specimen and provides more surface area for attachment of intraspinous ligaments and musculature. For modelling purposes the spinous process is trimmed slightly longer than the human. The disc to vertebra body height ratio was observed to be eleven percent for porcine and found to be twenty-five percent for human [122]. This ratio combined with less restrictive facet joints suggest the human spine has more inherent flexiblity than porcine. Although actual stiffness values for the porcine spine have not been determined, the apparantly greater porcine stiffness may enhance in-vitro modeling of in vivo human spines by accounting for a portion of trunk stiffness that is absent for in vitro studies.

Chapter 4. Fracture Creation

4.1. Problems With Fracture Creation

Significant experimental variables and inaccuracies are a feature of existing fracture creation techniques. Injury models inflicted vary from total removal or resection of a vertebral segment [79] to selective incisions of specific ligaments. According to Denis [38], three columns of the vertebra must be disrupted to create an unstable condition to justify internal spinal fixation. Studies [62, 67] which only disrupt the posterior ligament network or surgically remove two of the three columns do not meet Denis's criterion. Transverse resections [79] are reproducible, but complete removal of a vertebra is not clinically relevant due to absence of connective tissue and mating fracture surfaces that resist compressive loads. Transverse slice fractures [81] resist compression but lack connective tissue. Modelling fractures with osteotome cuts [68, 70] is not physiological and reproducibility has not been documented. Osteotome cuts, saw cuts and drill hole defects for the purpose of creating stress risers to initiate vertebral fractures during impact or quasi-static loading may be more physiological [90, 78, 62, 84, 103, 88, 71, 101]. Reproducibility using these techniques have been claimed by some researchers [90, 71, 101] but have not been proven or accurately documented.

The previous fracture creation technique used at the University of Alberta was described by Raso et al. [101] as a 1.5 cm groove cut with a hacksaw in the anterior body of the L1 vertebra. An intact spinal segment was enveloped in two cylindrical aluminum sleeves and subjected to an increasing compression load until a marked drop in load was

observed. Cinats et al. [104] described the defect: "With the spines frozen, a wedge of bone was removed from the anterior body of L1 with the apex of the wedge at the pedicles".

Reproducibility of the fracture was questioned by Cinats as he observed two distinct groups of greatly different clinical spinal stability. Observation by the author of the previous fracture creation technique disclosed extreme variations in the size, depth and position of the wedge defect resected from the anterior of the vertebra body. As a result, a study to improve fracture creation reproducibility fell within the scope of this thesis.

The importance of creating a physiologically relevant reproducible fracture which models a clinically unstable in vivo situation is paramount to ensure valid experimental results.

4.2. Development of Reproducible Fracture Model

Fracture creation procedure for multiple vertebra spinal segments was developed in three phases. Phases of fracture preparation are discussed here because of the importance of experimental details learned in these steps as they relate to clinical instability and reproducibility.

Initially, a careful fracture creation technique using single vertebrae was established for the previous fracture type (type one). Next, modifications to the new fracture creation technique produced a clinically unstable (type two) fracture in single vertebrae, however this fracture was considered too lithe for the multiple segment model. Ultimately, a type three fracture was developed and successfully applied to multiple vertebra specimens fractured at the L1 vertebral

level.

4.2.1. Clinically Stable Single Vertebra (type one) Fracture Creation

Poor previous fracture reproducibility prompted construction of jigs to ensure creation of a consistent (type one) defect shown in Figure 4.1 defined as a thirty degree wedge removed from the vertebra with the apex located at the midline of the vertebral body immediately anterior to the posterior cortical wall. An intact in vitro spinal canal wall and posterior longitudinal ligament was required in order to model in vivo vertebra fractures that protrude bone into the spinal canal upon collapse of the vertebra body. Compression loading causes the in vivo collapse of the vertebra body in typical compression/flexion fractures. The posterior elements experience tension loading due to bending about an intact in vivo fulcrum located posterior to the collapsed vertebral body. An in vitro fulcrum was produced at the apex of the defect. Incorporation of a drill hole radius in this investigation eliminated the problem of inconsistent closing of the defect. A drill jig (Figure 4.2) guided a 3 mm drill across the specimen. Pins inserted into the drill holes located the specimen in a saw cut jig. With the pins removed and the jig clamped tight, a wedge of bone was removed (Figure 4.3).

The defect was introduced in 28 single vertebra specimens (14 lumbar and 14 thoracic), taken from four spines, to determine effects of vertebra variability on fracture reproducibility. Thawed versus frozen specimens were investigated and fracture creation was monitored with acoustic emission. As vertebrae are inhomogeneous, anisotropic structures, microscopic reproduction of fractures was not expected. It

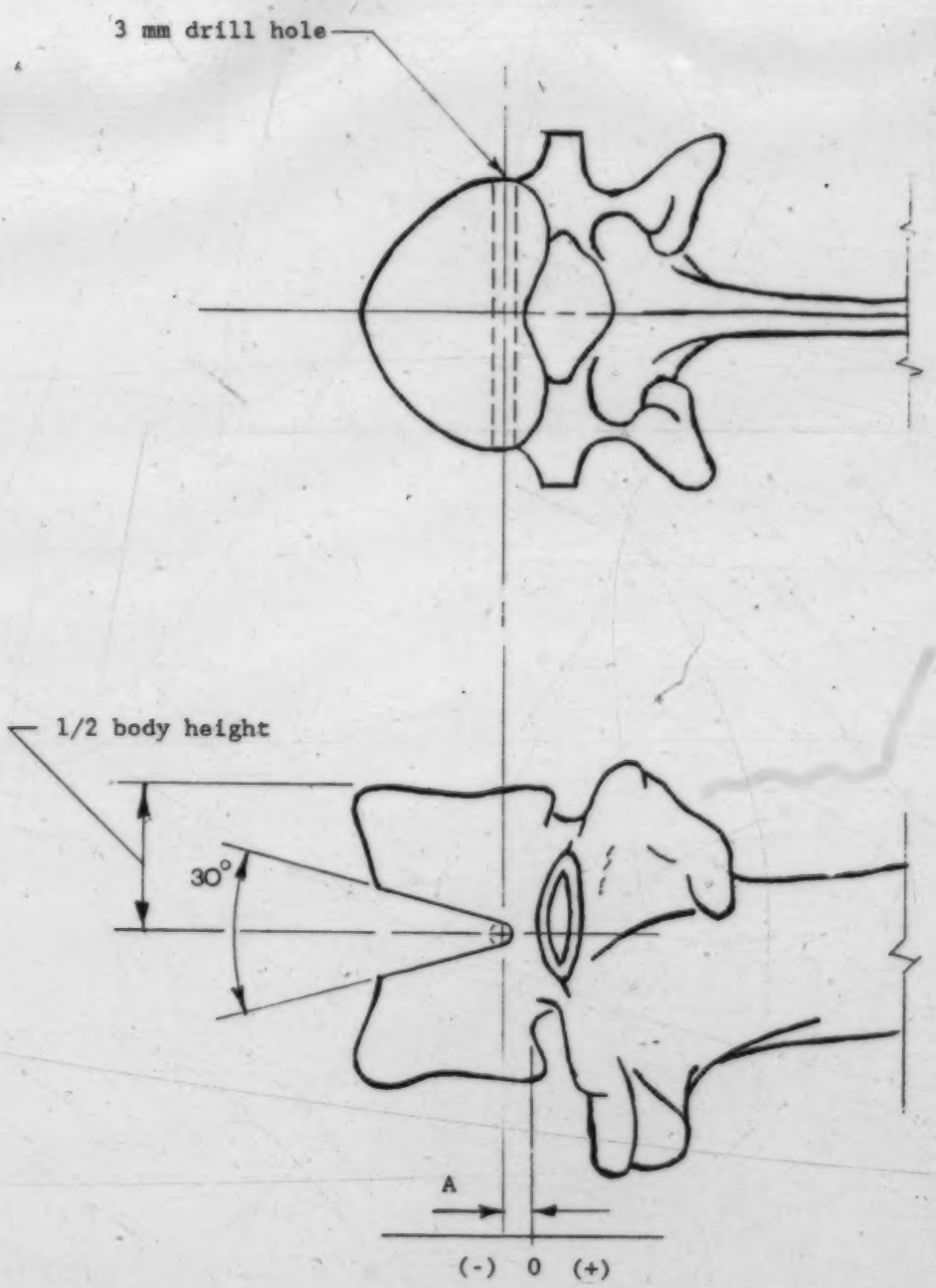


FIGURE 4.1. DEFECT IN LUMBAR VERTEBRA USED FOR FRACTURE TYPE ONE

FIGURE 4.2. DRILL GUIDE TO LOCATE APEX OF WEDGE DEFECT

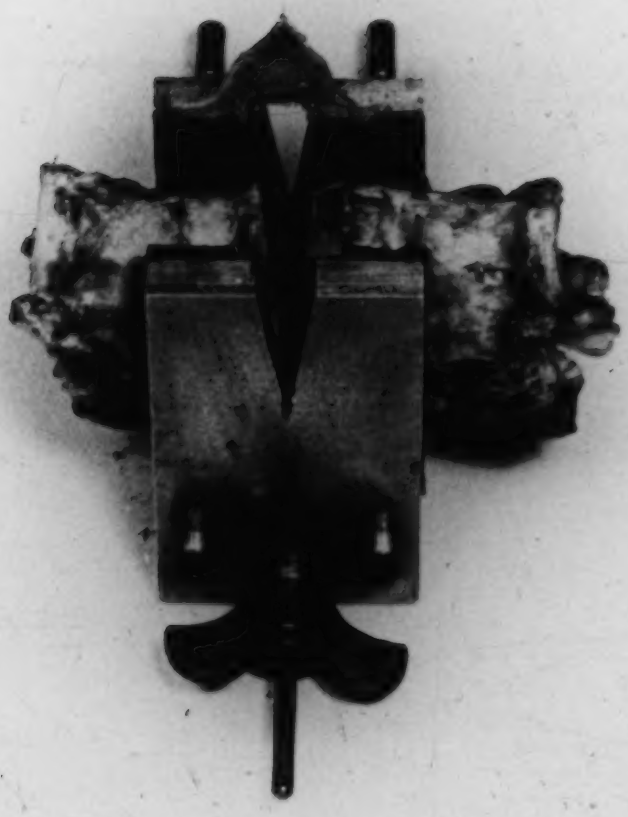


FIGURE 4.3. SAW CUT JIG USED TO REMOVE WEDGE DEFECT FROM VERTEBRA

was anticipated, however that similar fracture paths would be produced.

Single vertebra specimens, with all soft tissue removed, were placed in an Instron testing machine and held with superior and inferior end caps (Figure 4.4) and subjected to quasi-static axial compression (crosshead feed rate of 2.5 mm per minute) applied at the vertebral body end plates until fracture occurred. The pin protruding from the end cap fixed the spinal canal. The serrated surface prevented specimen slippage during loading (except during acoustic emmision testing which had smooth polymer surfaces for noise insulation). Contact stress concentrations at the end cap - vertebra interface were introduced, but local damage in contact with the end plates should not affect the results. More importantly, experimental variabilities arising from soft tissue between vertebra were eliminated. Vertical and lateral fracture displacement at the anterior body was accomplished with on-line measurement with a displacement transducer which is described in Chapter 5. The displacement transducer shown in Figure 4.5 is attached to a single vertebral specimen. A fracture separating the vertebra into distinct components, allowing secure attachment of the transducer frame to one component, was obtained through a trial and error process. An acoustic emission sensor is also shown attached to the spinous process. Acoustic emission measurement of fracture propagation is discussed later in this chapter.

4.2.2. Clinically Unstable Single Vertebra (type two) Fracture Creation

Based on Denis's [38] three column instability criterion further vertebra testing [107] was performed to develop a reproducible clini-

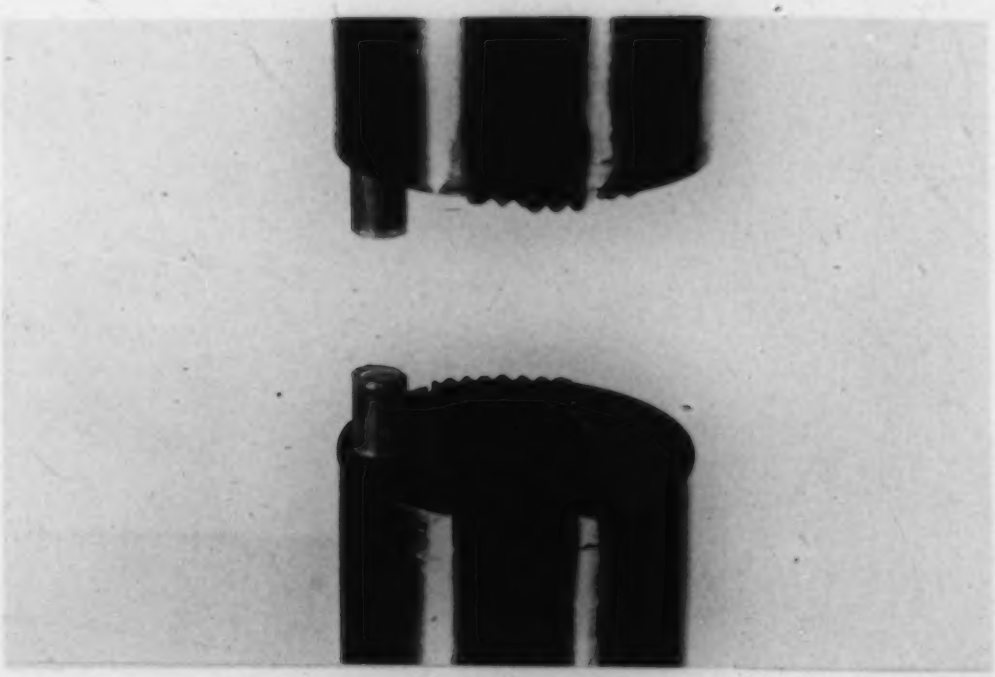


FIGURE 4.4. LOADING END CAPS FOR FRACTURE CREATION

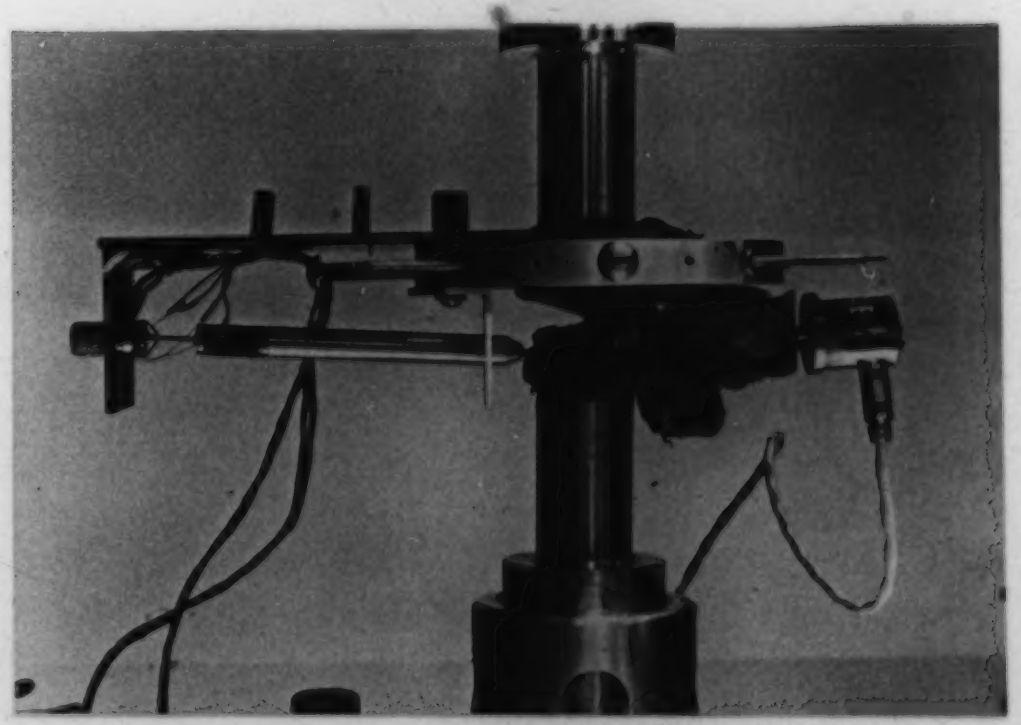


FIGURE 4.5. FRACTURE CREATION SETUP SHOWING DISPLACEMENT TRANSDUCER

cally unstable fracture. The desired fracture would extend through the pedicles, transverse processes, lamina and spinous process leaving the posterior ligaments intact ensuring a clinically unstable fracture. Severity of the defect was increased incrementally using single lumbar vertebra specimens until the desired fracture was obtained.

The eventual defect (Figure 4.6) which produced the desired fracture was introduced by first drilling a 3 mm diameter hole laterally through the transverse processes such that the center of the hole was located at the vertical midline of the pedicles and penetrated the center of the spinal canal. The saw cut jig was modified to introduce a twenty degree wedge defect in the vertebra specimen symmetrically splitting the pedicles to ensure equal distribution of pedicle mass on each side of the defect to help prevent fracture through a resulting thin pedicle structure. A horizontal transverse saw cut was introduced posteriorly from the drill hole through to the lamina where a shallow notch acted as a stress riser to promote bending and fracture of the posterior elements. In the earlier model (type one), the significant mass and structural integrity of the intact transverse processes and lamina was believed to have prevented fracture propagation into the posterior elements.

4.2.3. Multi-segment Three Column (type three) Fracture Creation

Application of the type two single vertebra fracture creation regime to seven-segment spinal columns initially resulted in specimens with no inherent resistance to tensile loads. Greater bending energy in the longer spinal column caused more destructive fracture initiation and propagation resulting in negligible connective fibre and soft tissue

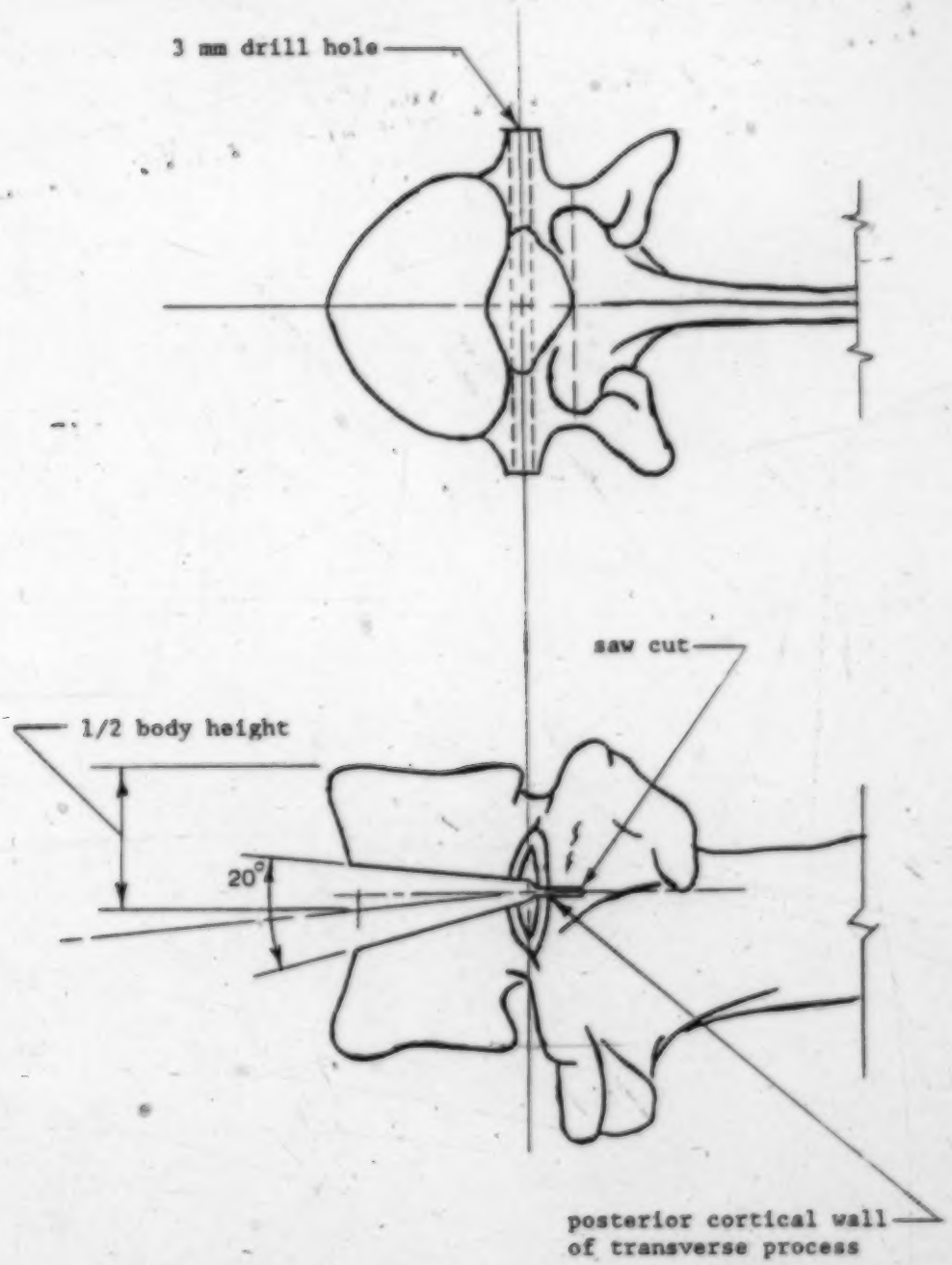


FIGURE 4.6. DEFECT USED TO PRODUCE FRACTURE TYPE TWO

after fracture. A defect providing an acceptable fracture (type three) was developed and modified [107] by trial and error. This produced sixty per cent greater fracture surface area in the posterior elements than type two fractures (Figure 4.7). The greater fracture area and intact inter-spinous ligaments and posterior flesh provided additional connective bone fibre and soft tissue. Elimination of the saw cut lamina stress riser moved the fulcrum more anterior to the posterior aspect of the transverse processes. The final optimized defect in a typical three segment specimen is shown in Figure 4.8. Fracture reproducibility was confirmed using six frozen specimens (T10-L4) with a defect introduced at the L1 vertebral level. The specimens were subjected to incremental thawing of soft tissue at the L1 vertebra (with the remaining portion frozen) to study its effects on fracture creation. Figure 4.9 shows the fractured posterior elements and lamina (three column fracture) of a specimen with its tissue removed.

4.2.4. Fracture Creation Test Results

4.2.4.1. Type One Fracture Results

All vertebra suffered fractures from the apex of the defect to the inferior intervertebral notch except two thoracic vertebra which suffered severe loss of load resistance but showed no visible evidence of fracture. The horizontal position of the drill hole apex with respect to the intervertebral notch (dimension A, Figure 4.1) was found to be generally related to fracture load (Figure 4.10). Variation in defect apex position was due to the significant morphological differences over the specimen range of thoracic (T9) to lumbar (L4) vertebrae. Greater loading was required to fracture a specimen with a more

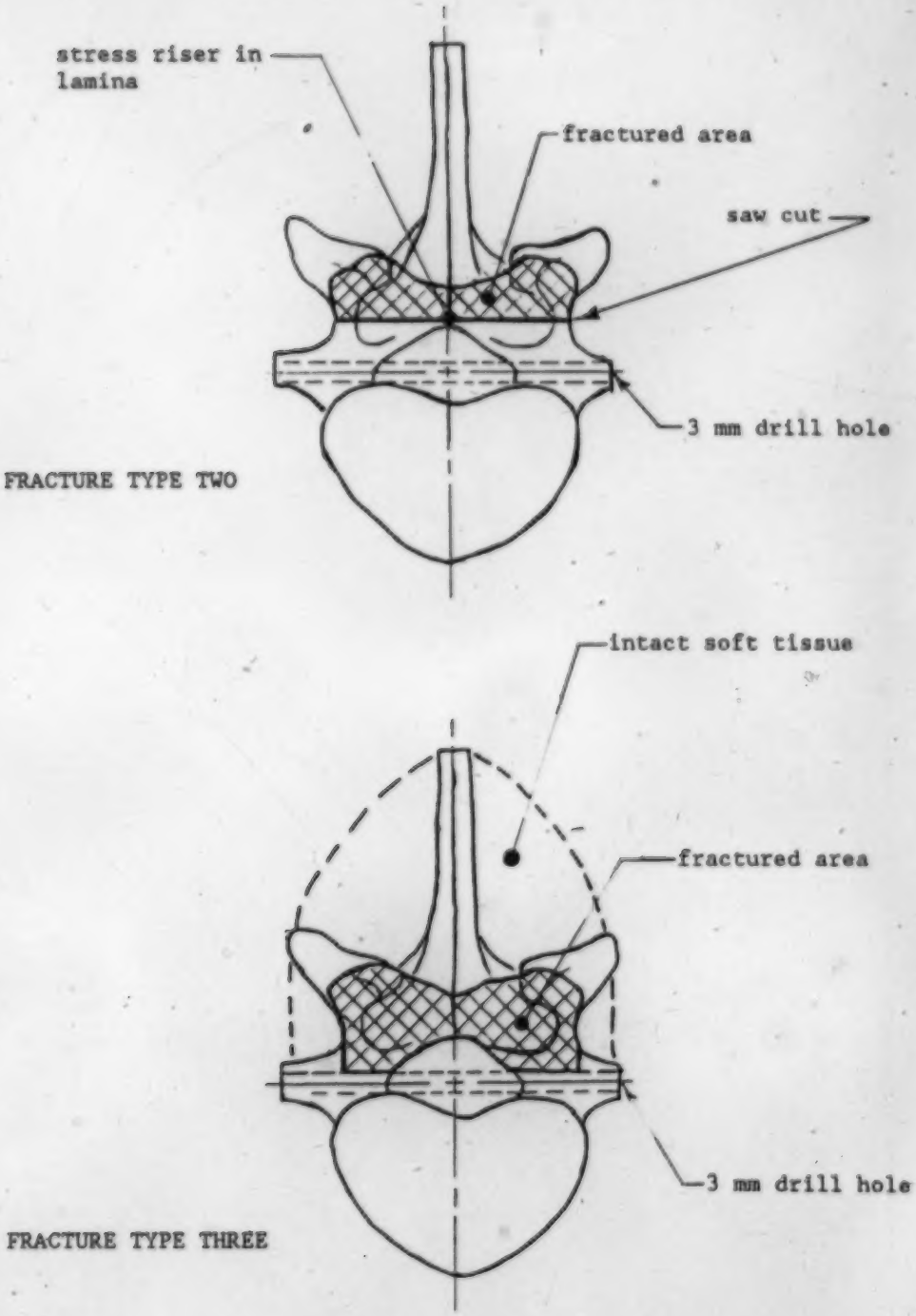


FIGURE 4.7. RESULTANT FRACTURE SURFACE AREA FOR FRACTURE TYPES TWO AND THREE

FIGURE 4.8. WEDGE DEFECT INTRODUCED IN THREE VERTEBRA SPECIMEN

FIGURE 4.9. FRACTURE THROUGH POSTERIOR ELEMENTS OF VERTEBRA SPECIMEN

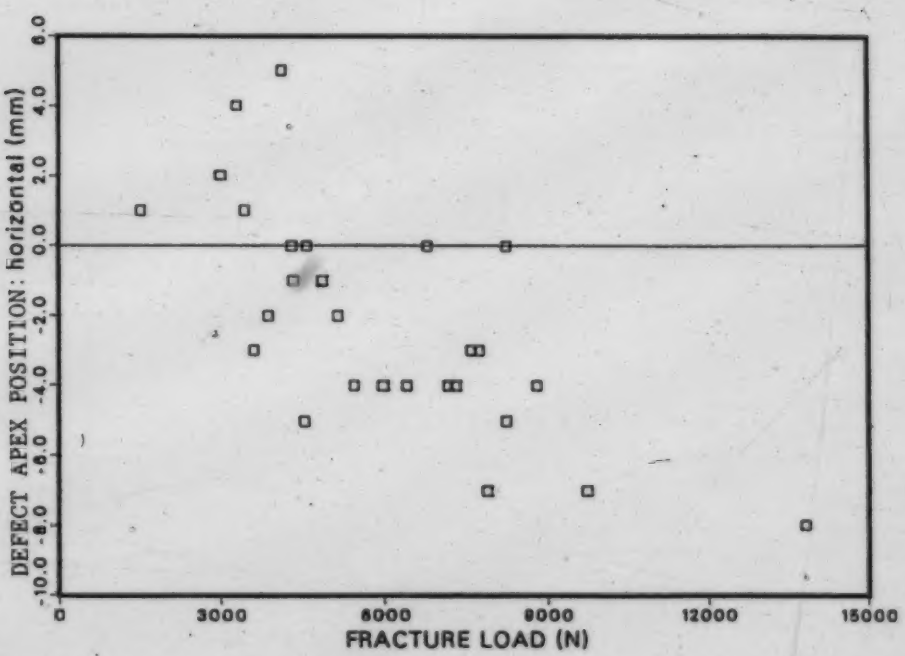
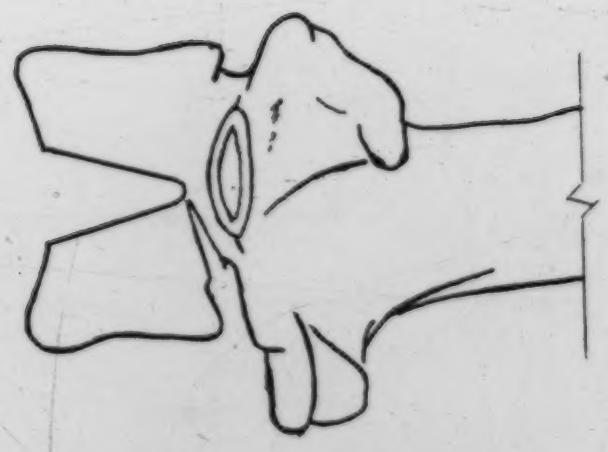


FIGURE 4.10. EFFECT OF DEFECT APEX POSITION RELATIVE TO INFERIOR VERTEBRAL NOTCH ON FRACTURE LOAD (refer to dimension A, Figure 4.1.)

anterior defect apex. A more posterior apex severed the cylindrical wall surrounding the spinal canal reducing vertebra resistance to compression loading. Two distinct fracture modes (Figure 4.11) were observed. The relationship between apex position and fracture load suggested a transition from a compressive shear failure (timber like) to a bending tension failure (split) through the pedicles. Five vertebra (four thoracic and one lumbar) suffered characteristic shear failures with a mean compression load of 8958 N, a relatively slow drop in load resistance (Figure 4.12) and little vertical fracture displacement (Figure 4.13). Eleven vertebrae (nine lumbar and two thoracic) suffered complete bending tension failures with a mean compression load of 4113 N, initiating a fracture at the inferior notch and propagating to the apex of the defect. Typical tension failures showed rapid loss of load resistance (Figure 4.14) and greater displacement (Figure 4.15). Manipulation of the fractured specimens by hand showed bending (split) failures possessed little or no stiffness at the fracture hinge point, where a shear (timber) failure retained relatively greater stiffness due to a significant amount of connective fibre helping to explain Cinat's [104] observation of widely varying groups of fracture stability using the similar defect. A summary of fracture loads and displacement for the entire test population and segregated lumbar and thoracic groups is shown in Table 4.1. Vertebral dimensions and statistical variations for the same groups are shown in Table 4.2. Specimen variation within specific lumbar and thoracic groups was small, but a combined lumbar and thoracic group showed significantly larger variations. No trends were observed relating fracture load and displacement to variations in vertebral morphology. Two tests were

TIMBER FRACTURE THROUGH PEDICLE



SPLIT FRACTURE THROUGH PEDICLE

FIGURE 4.11. TYPE ONE FRACTURE MODES

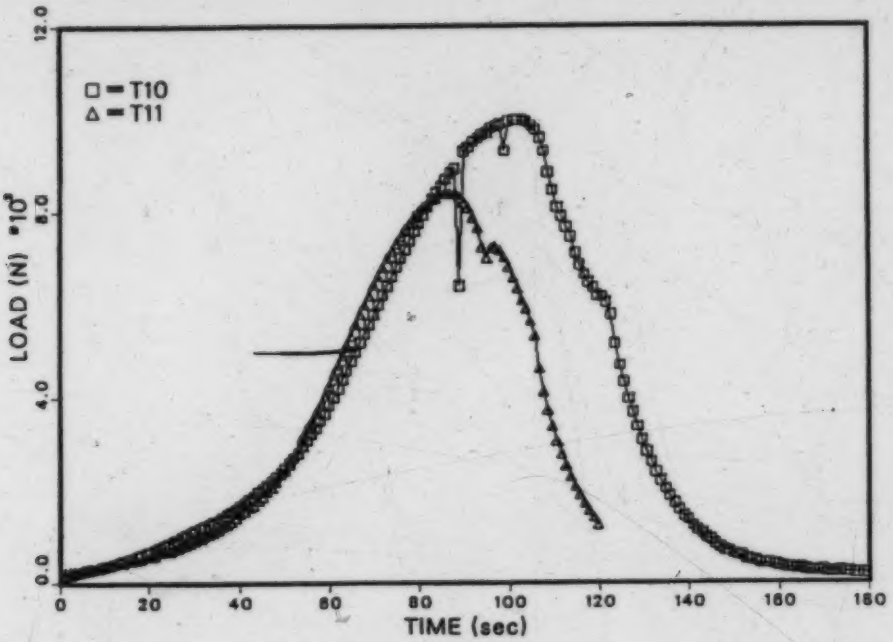


FIGURE 4.12. TYPICAL LOAD RESISTANCE OF TWO TIMBER TYPE FRACTURES

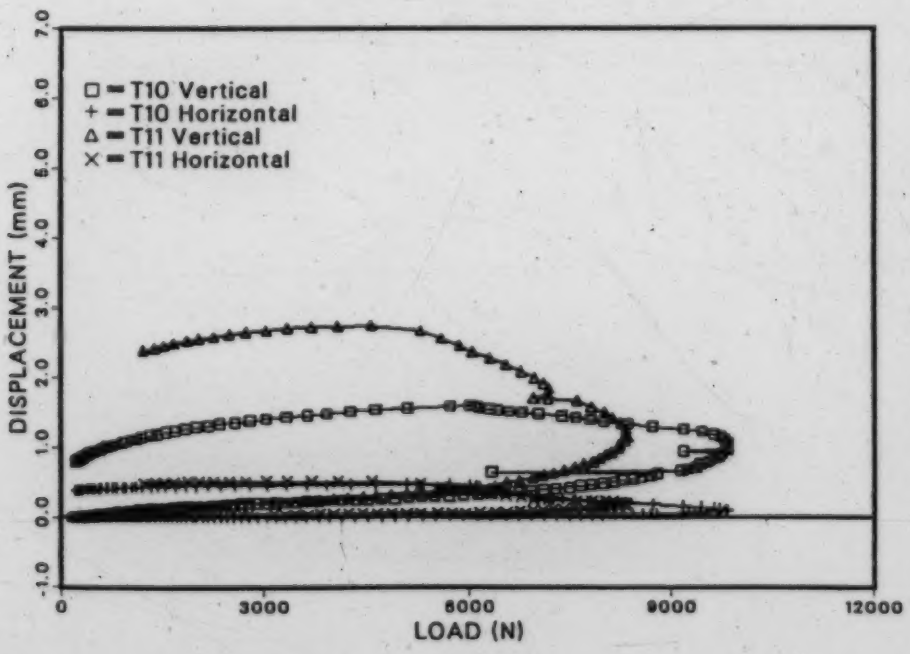


FIGURE 4.13. FRACTURE SITE DISPLACEMENT OF TWO TIMBER FRACTURES

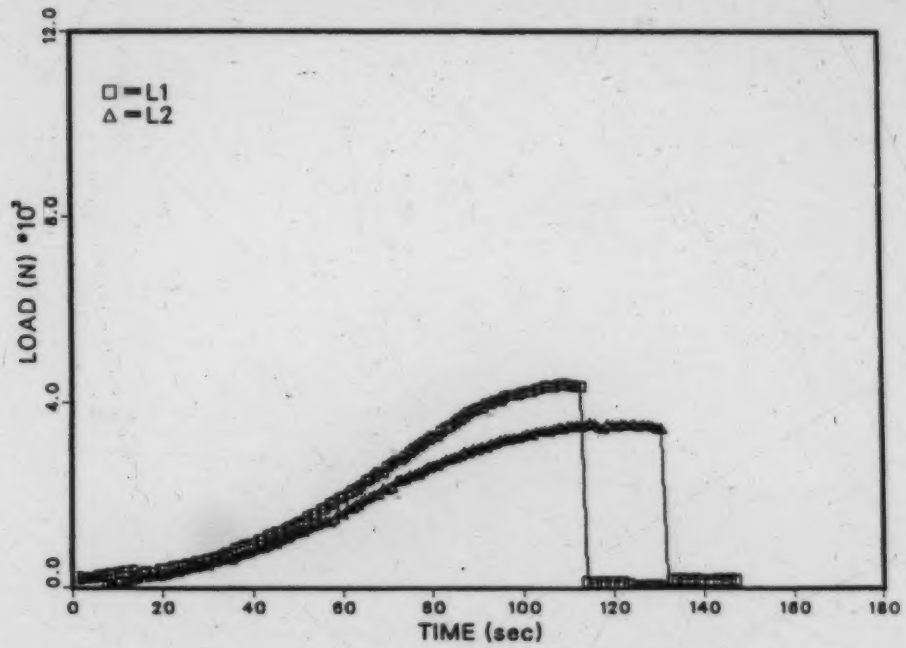


FIGURE 4.14. LOAD RESISTANCE OF TWO SPLIT TYPE FRACTURE

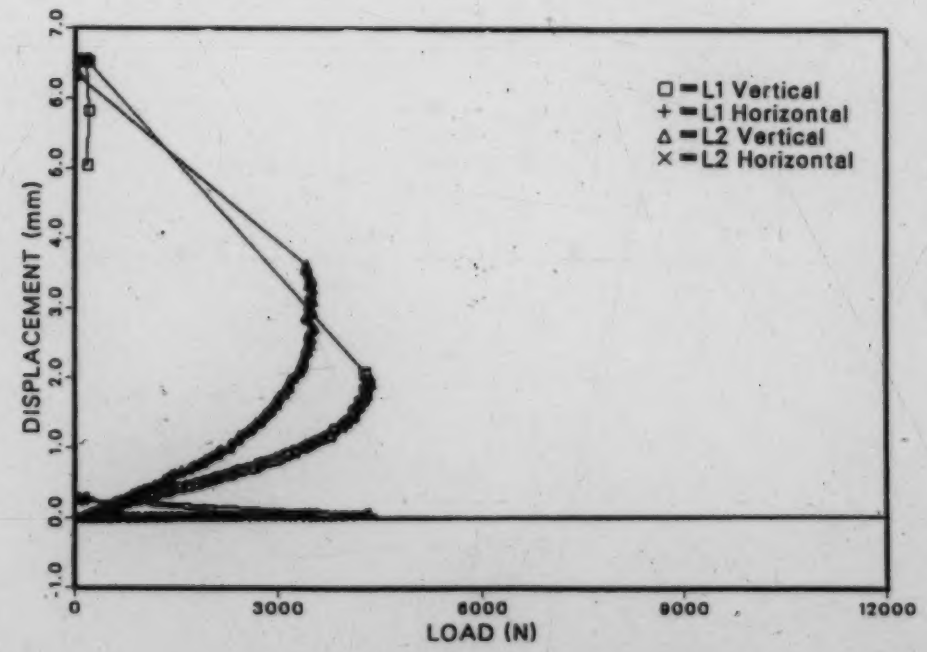


FIGURE 4.15. FRACTURE SITE DISPLACEMENT OF TWO TYPICAL SPLIT FRACTURES

TABLE 4.1. SUMMARY OF SPECIMEN MORPHOLOGY FOR TYPE ONE FRACTURE

PHASE ONE (single vertebra specimens)		MEAN (mm)	MAXIMUM (mm)	MINIMUM (mm)	STANDARD DEVIATION (mm)
ALL VERTEBRAE n = 28	Body Height	42.32	49	36	4.02
	Body Width	35.39	40	30	2.38
	Body Length	28.32	32	24	2.06
	Spinal Canal (A/P)	13.62	20	11	2.01
	Spinal Canal (transverse)	23.00	28	18	3.05
LUMBAR VERTEBRAE n = 14	Body Height	45.71	49	42	2.23
	Body Width	36.57	40	34	1.87
	Body Length	29.93	32	28	1.00
	Spinal Canal (A/P)	14.00	20	12	2.62
	Spinal Canal (transverse)	24.38	28	19	3.46
THORACIC VERTEBRAE n = 14	Body Height	38.93	44	36	1.94
	Body Width	32.21	38	30	2.29
	Body Length	26.71	29	24	1.49
	Spinal Canal (A/P)	13.38	16	11	1.61
	Spinal Canal (transverse)	22.15	25	18	2.54

TABLE 4.2. SUMMARY OF TYPE ONE SPECIMEN FRACTURE LOADS AND DISPLACEMENTS

PHASE ONE (single vertebra specimens)		MEAN (mm)	MAXIMUM (mm)	MINIMUM (mm)	STANDARD DEVIATION (mm)
ALL VERTEBRAE n = 28	Fracture Load (N)	6228	13884	1513	2800
	Displacement at Fracture	1.78	3.66	0.81	0.78
	Displacement After Fracture	3.34	6.65	1.26	1.74
	Displacement During Fracture	1.56	5.06	0.04	1.35
LUMBAR VERTEBRAE n = 14	Fracture Load (N)	5400	8856	3004	1908
	Displacement at Fracture	1.97	3.66	1.33	1.01
	Displacement After Fracture	3.78	6.65	1.85	2.20
	Displacement During Fracture	1.81	5.06	0.28	1.57
THORACIC VERTEBRAE n = 14	Fracture Load (N)	7056	13884	1513	3341
	Displacement at Fracture	1.33	2.39	0.81	0.60
	Displacement After Fracture	2.22	5.61	1.26	1.40
	Displacement During Fracture	0.89	3.90	0.04	1.24

performed on frozen lumbar vertebrae but showed no significant difference from thawed results.

4.2.4.2. Type Two Fracture Results

When the modified fracture creation procedure appeared to provide the desired fracture, tests were conducted to confirm its repeatability [107]. Twelve lumbar vertebra specimens from four sow spines were prepared and subjected to quasi-static compression until failure.

Vertebral specimen variability is shown in Table 4.3. The minimal variation in size suggested by the small standard deviation confirms the homogeneity of the specimens. Fracture and loading results are shown in Table 4.4. The range and reproducibility of fracture load and vertical fracture site displacement is shown in Figures 4.16 and 4.17. Fracture creation showed good reproducibility considering the inhomogeneous and anisotropic properties of bone. The mean fracture load was 1808 N with a standard deviation of only 334 N. The mean displacement at fracture was 6.3 mm with a standard deviation of 0.99 mm. Fracture initiated at the base of the superior surface of the spinous process and propagated through the lamina to the defect leaving a small amount of connective tissue near the defect apex. The apex of the defect acted as fulcrum which transformed compressive loading at the vertebral body into a bending at the cross-section including the posterior elements. Tension Failure was observed in all specimens.

4.2.4.3. Type Three Fracture Results

Load and displacement results during fracture creation are shown in Table 4.5 and displayed graphically in Figures 4.18 and 4.19. An

TABLE 4.3. SUMMARY OF VERTEBRA MORPHOLOGY FOR TYPE TWO FRACTURE TEST

PHASE TWO (single vertebra specimens)		MEAN (mm)	MAXIMUM (mm)	MINIMUM (mm)	STANDARD DEVIATION (mm)
LUMBAR VERTEBRAE n = 12	Body Height	43.04	47	40	2.02
	Body Width	35.62	38	33	1.33
	Body Length	25.29	27	23	1.41
	Spinal Canal (A/P)	13.88	15	12	1.05
	Spinal Canal (transverse)	24.50	30	22	2.18

TABLE 4.4. SUMMARY OF TYPE TWO FRACTURE LOADS AND DISPLACEMENTS

PHASE TWO (single vertebra specimens)		MEAN (mm)	MAXIMUM (mm)	MINIMUM (mm)	STANDARD DEVIATION (mm)
LUMBAR VERTEBRAE n = 12	Fracture Load (N)	1808	2415	1245	334
	Displacement at Fracture	4.93	7.05	3.63	0.86
	Displacement After Fracture	6.30	7.50	4.50	0.99
	Displacement During Fracture	1.31	2.97	0.20	1.00

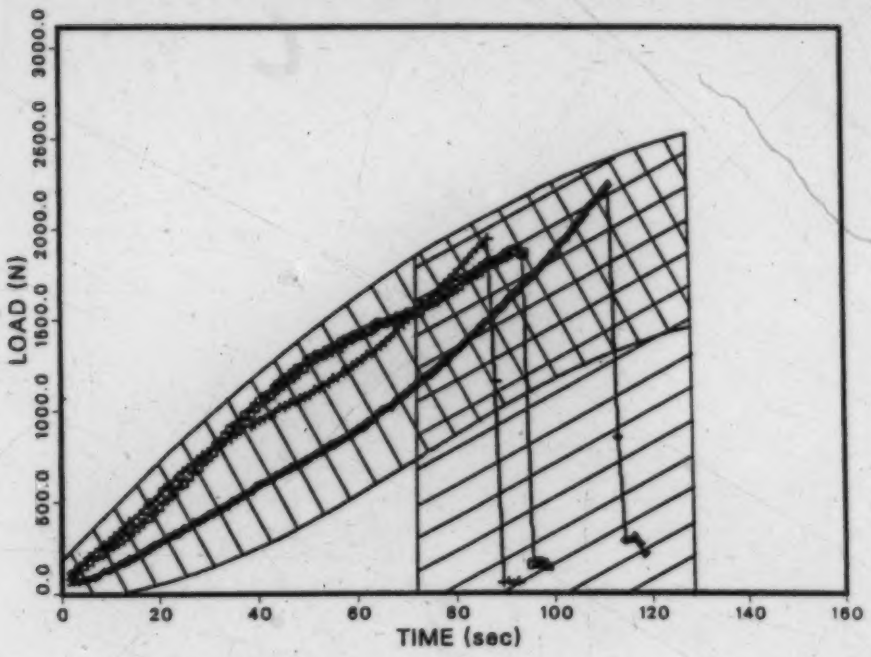


FIGURE 4.16. REPEATIBILITY OF VERTEBRA RESISTANCE TO LOAD FOR FRACTURE TYPE TWO

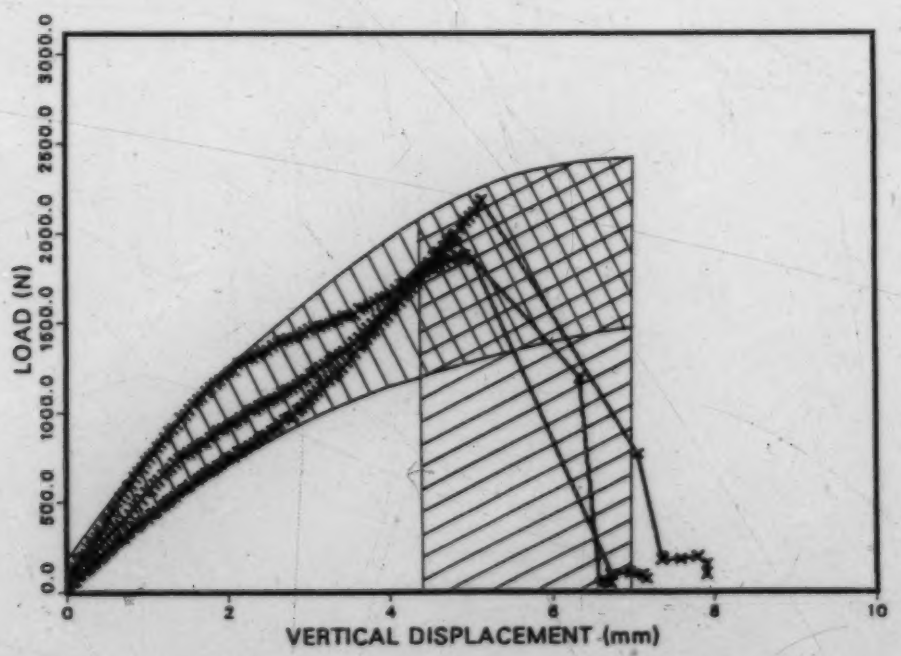


FIGURE 4.17. REPEATIBILITY OF TYPE TWO FRACTURE DISPLACEMENT

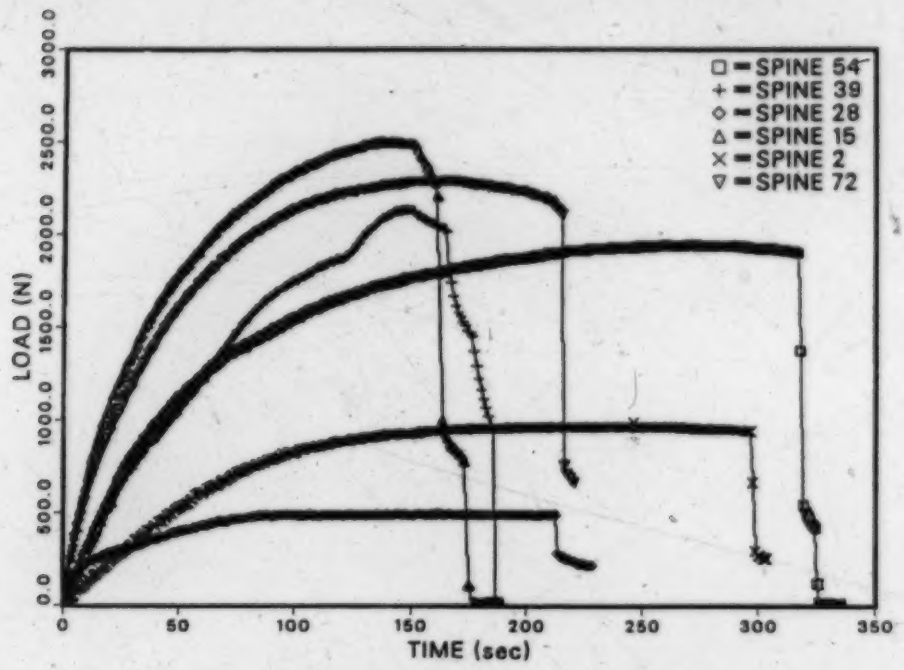


FIGURE 4.18. TYPE THREE FRACTURE LOADING OF SEVEN SEGMENT SPINES

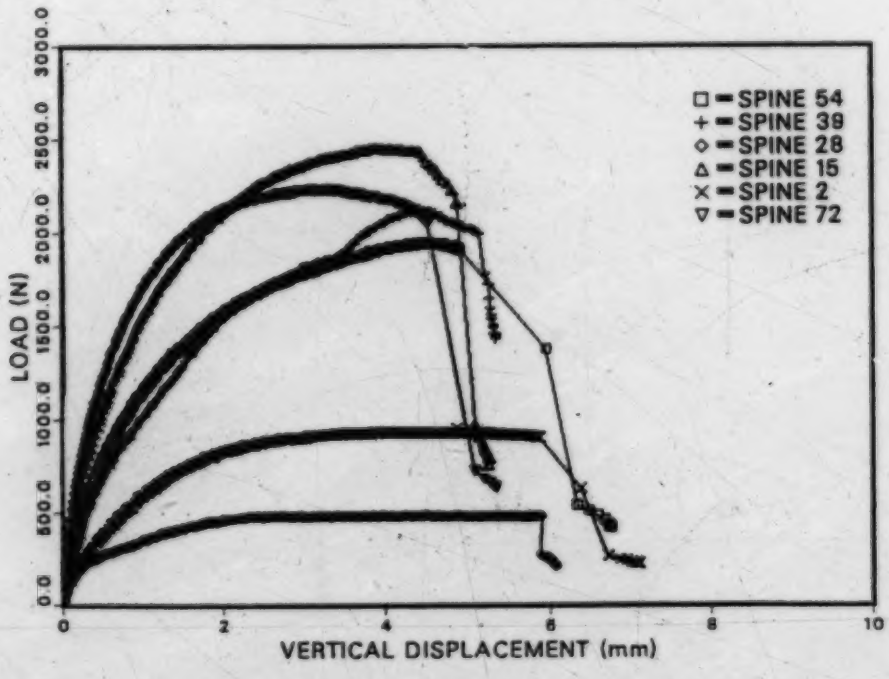


FIGURE 4.19. VERTICAL FRACTURE DISPLACEMENT (type three) OF SEVEN SEGMENT SPINES

TABLE 4.5. SUMMARY OF MULTIPLE VERTEBRA FRACTURE TESTING (Type Three)

Spine Number	Body Height (mm)	Body Length (a/p) (mm)	Body Width (lateral) (mm)	Fracture Load (N)	Displ. at Fracture (mm)	Displ. After Fracture (mm)	Displ. During Fracture (mm)
15	40	38	38	2212	4.96	5.34	0.39
28	40	40	38	485	5.99	6.17	0.18
39	40	40	38	2011	5.10	5.29	0.20
2	42	40	42	935	6.00	7.25	1.25
54	40	42	38	1900	4.95	6.77	1.82
72	38	36	36	2096	4.61	5.19	0.58
MEAN	40	39.3	38.3	1606	5.27	6.00	0.74
MAX	42	42	42	2212	6.00	7.25	1.82
MIN	38	36	36	485	4.61	5.19	0.18
ST.DEV.	1.26	2.07	1.97	716	0.586	0.870	0.661

increase in freezing at the L1 vertebral level correlates with increased load resistance and decrease in time to fracture. Although each specimen exhibited unique graphical results, the desired three column fracture was achieved in each case with a highly reproducible fracture displacement indicated by the 0.87 mm standard deviation. This also indicates significant experimental flexibility with regards to degree of freezing at the fracture site. The fracture created does not perfectly fit any particular catagory defined by Denis. It is best described as a compression failure in both anterior and middle columns with a distraction (tension) failure in the posterior elements hinged in the posterior region of the pedicle. The compression fracture according to Denis [38] is similar but differs as it has an intact middle column which acts as a hinge. The anterior and posterior columns similarily fail in compression and distraction (tension). Splitting of the pedicles and transverse prossesses with a horizontal fracture through the lamina is similar to Denis's seat belt fracture except for the hinge in the anterior column. The fracture created is a combination of both the compression and seat belt type fracture and is generally representative of unstable fractures which are found in the clinic.

4.3. Application of Acoustic Emission to Fracture Testing

As sound waves (pressure waves) are emitted during fracture initiation and propagation it was decided to evaluate the effectiveness of monitoring fracture creation with acoustic emission. Verification of fracture creation with acoustic emission could eliminate the need to obtain x-ray confirmation. This would enable testing of a fixation

device to proceed immediately following fracture creation. The threshold for recording acoustic emission was also evaluated. A low threshold would allow effective monitoring of additional fracture creation and rubbing of fracture surfaces that may occur during testing of a fixation device. This may contribute to degradation of the spinal model. Monitoring these events could detect a loss of experimental control. This would especially apply to repetitive or multiple testing of fracture fixation devices on one specimen. Visco-elastic soft tissue between vertebrae provide effective insulation from the mechanical noise and vibration emitted by loading devices making the spine an ideal candidate for acoustic emission.

Single vertebrae were isolated from machine noise during loading with tygon tubing placed over the spinal canal locating pin and 1.5 mm lexan and rubber sheets bonded to the surface of the loading end caps. An acoustic emission pickup device was attached to a pin adapter and inserted longitudinally into the spinous process to record sound waves propagating horizontally (Figure 4.5). It was not the purpose of this study to provide a precise description of acoustic principles and results, but only to establish the possibility of monitoring fracture creation.

4.3.1. Acoustic Emission Results

Figure 4.20 shows typical acoustic emission response (number of events) to loading and fracture creation. Two distinct fractures are shown in this illustration. A significant reduction in load resistance occured during the first fracture (possibly a single pedicle) and a second fracture caused catastrophic failure (possibly the second

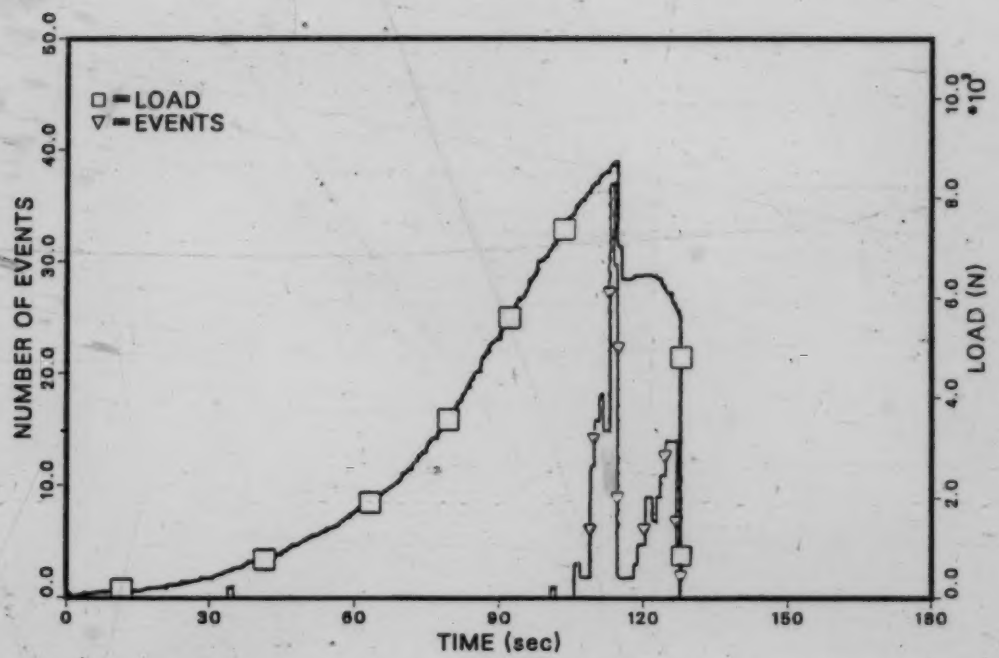


FIGURE 4.20. ACOUSTIC EMISSION RESPONSE SHOWING TWO SIGNIFICANT FRACTURES DURING FRACTURE CREATION

pedicle). Some noise from minor fractures (inaudible to the human ear) was recorded prior to a major fracture. A crude estimate of the threshold level for recording acoustic emission in this study is defined as the noise generated by the scratching of a lead pencil on the surface of an intact vertebral specimen. This is low compared to the threshold observed in previous studies [98] on the same loading device using steel specimens. The commonly accepted threshold for acoustic emission response on steel specimens is obtained by breaking a 0.5 mm pencil lead on the specimen. Results show that machine or background noise is effectively isolated ensuring accurate acoustic reception of vertebra fracture response. This indicates that acoustic emission could serve in verifying the creation of a fracture and could possibly qualify the type of fracture with further experimentation. The relatively low threshold indicates that acoustic emission could be used as an effective tool for monitoring experimental control at the fracture site.

Chapter 5. Measurement of Fixation Device Effectiveness

5.1. Earlier Methods

During many early experiments, investigators [78, 62, 67, 83, 105, 93, 66] measured motion of the loading device (crosshead), producing load deflection results that estimated the stiffness of the fixated spine. Strain gauges were implemented in some studies [78, 94, 95] to estimate load sharing between the spine and fixation device. A three dimensional displacement transducer devised by Koogle [108] and employed by Nagel [36] to measure motion between two adjacent vertebrae was mounted posteriorly on intact cadavers. The transducer had a linear displacement accuracy of 0.69 mm and a rotational accuracy of 0.83 degrees. Difficulties were encountered in long term drift of the measurement system. Extensometers (strain clips) were utilized by Munson [79] and Purcell [67] to measure motion between vertebrae, but were criticized for being excessively stiff, generally having a short range and measuring in only one direction. Some researchers mounted potentiometers and LVDT's to determine specific spinal rotations and translations at various locations. Most recent investigators [70, 72, 82, 81, 64, 101] have attempted to evaluate fixation devices using a global measurement system in which gross displacements and rotations are measured for vertebrae on each side of the fracture. Fracture flexibility can then be estimated but results can be severely affected by local soft tissue injury, malformation and preconditioning. The above problems manifest themselves by relatively poor repeatability and wide scatter of displacement data despite controlled monotonic loading. None of the global methods are more accurate than +/- 1 mm and do not

measure motion at the fracture site.

Implementing an accurate means of measurement is crucial in quantifying the effectiveness of fixation instrumentation and providing an objective valid comparison with other devices. Before attempting measurement a clear definition of effectiveness and performance of a fixation device is necessary. Current tests are conducted with physiological loads but the basis of evaluation, in most programs is the stiffness of the instrumented spine.

The previous method [101] for evaluation of fracture fixation devices relied on a global measurement approach using photographs to record the displacements of markers on both sides of the fracture site (Figures 5.1 and 5.2). Relative motion between two normal intact vertebrae are compared with the relative motion between a normal and a fractured vertebra providing a measure of flexibility introduced with the fracture. This method, as with most global methods, involved tedious photographic - digitizing techniques which are subject to significant experimental errors and coarse data sampling. Measurement accuracy was +/- 1.3 mm.

5.2. Fundamental Basis for Evaluation of Instrumentation

It has been previously proposed [101] that the best measure of effectiveness is the ability of the fixation device to limit relative motion at the fracture site during a patient's normal daily activity. It follows that discrete measurement of fracture site motion is the most appropriate basis for evaluation and comparison. The method in this study is based on a direct application of the fundamental basis of evaluation stated above. Relative motion of the fracture surfaces

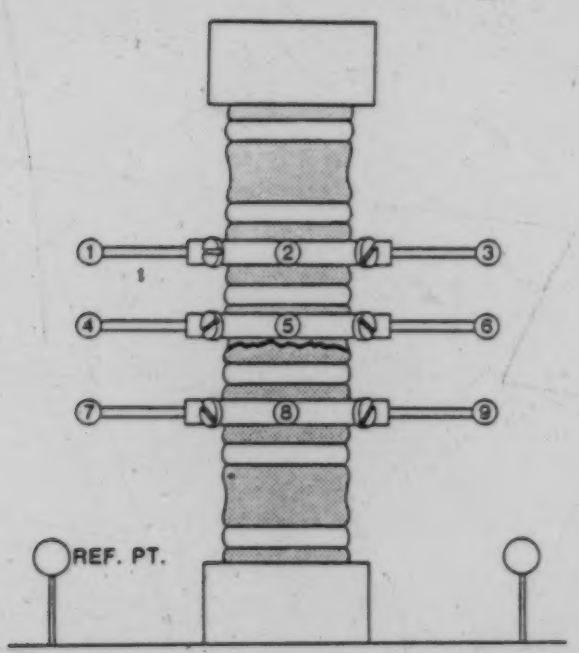


FIGURE 5.1. PREVIOUS GLOBAL MEASUREMENT TECHNIQUE SHOWING SPINE AND MARKER RINGS [101]

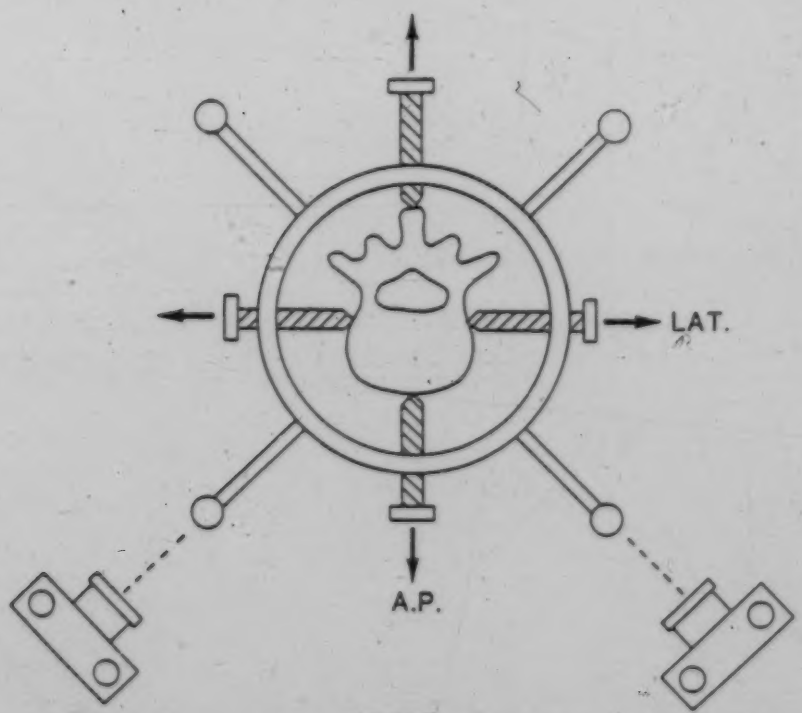


FIGURE 5.2. MARKER RING AND CAMERA ORIENTATION FOR PREVIOUS GLOBAL MEASUREMENT TECHNIQUE [101]

is measured directly. Prior to making this measurement, however, the fracture deformation is monitored in order that the value of the measured relative displacement is obtained at the location where it is greatest.

A comprehensive error analysis shows that measurement errors are small and differences in results can be attributed to differences in instrumentation. This conclusion also requires a repeatable fracture as discussed in chapter 4.

5.3. Design Criteria for Local Measurement

From observation, it appeared that maximum relative motion between fracture surfaces was of the order of 5 to 10 mm. It is known that total elimination of motion is not possible, nor is it desired since micro-motion between fracture surfaces enhances the healing process. With this in mind, a measurement resolution in the order of 0.025 mm (0.001 in) along with a range of 10 mm appeared to be suitable for tests to be performed with this apparatus. Optical, video or Selspot photographic techniques were eliminated as accuracy and resolution of less than 1 mm was difficult to achieve. It was decided to employ an electronic displacement transducer with on-line data processing. A maximum allowable transducer load at the fracture site would be 0.56 N (0.125 lb) compared to the maximum in vivo compression load applied to the vertebra body of 2700 N [9]. This ensured experimental results would not be affected due to restriction of fracture site movement. As the existing global system was considered useful in providing vertebral kinematic results it was required that the local measurement method be integrated into the existing system.

An experiment using a photographic/cross hair technique (Figure 5.3) to monitor local fracture site motion was performed on a seven vertebra porcine spinal segment, on which the middle (L1) vertebra was fractured.

This study would determine which components of motion required measurement for the fracture model in this investigation and would also confirm the sensitivity and range requirement of the transducer system to be designed. Harrington distraction instrumentation was implanted over 5 vertebrae, as it has been shown to be the most flexible in torsion [101] and would presumably permit the greatest relative motion at the fracture site. For local measurement to be most effective, the points at which maximum relative motion between fracture surfaces occurs must be determined. To make this assessment, two cross-hairs were fabricated from type 304 stainless steel surgical tubing (0.5 mm diameter) and inserted in small holes drilled in the inferior and superior components of the vertebra body. Three 35 mm cameras were used to produce photographic records of cross hair motion in the frontal, lateral and sagittal planes. The specimen was subjected to incrementally increasing static torsion loading. Photographs were taken after a period of 3 minutes to allow for creep. Test results were reduced to show translation components of all motion. Primary motion was determined to be rotation about the longitudinal axis. Vertical motion was found to be negligible. The lateral translation component of rotation (x-direction) due to a physiological torsion load of 11.3 Nm (8.33 ft.lb.) was 5.0 mm (0.2in) in one direction. This would amount to a 10 mm range when subjected to reversed torsion. The anteroposterior translation component (y-direction) was 1.1 mm and

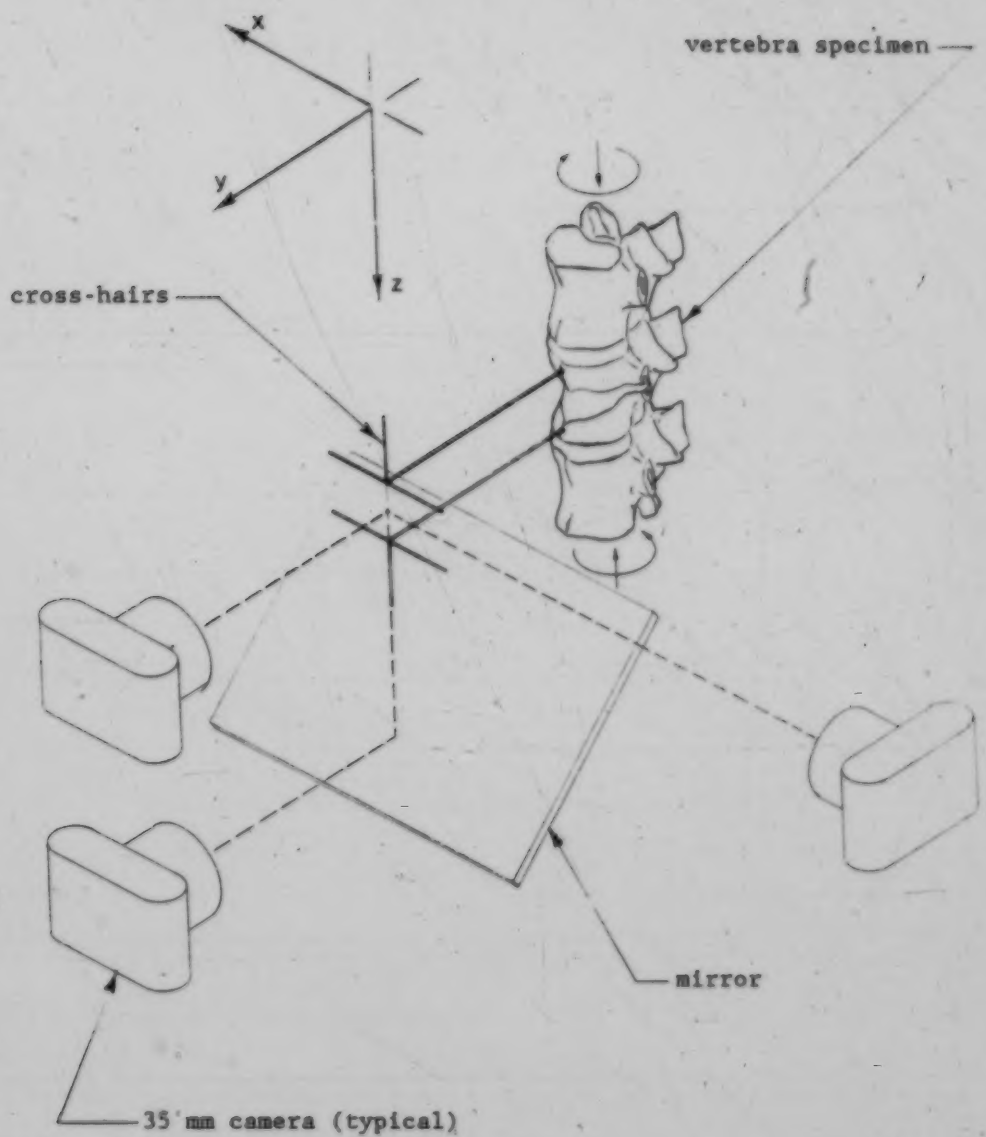


FIGURE 5.3. PHOTOGRAPHIC/CROSS-HAIR TECHNIQUE TO RECORD LOCAL FRACTURE SITE MOTION

considered negligible in comparison with x displacement (11 percent of x range). Pure (lateral) bending about the y-axis was not observed. This is the only motion for which a translation component would not be recorded by a biaxial transducer in the frontal plane. Previous observation of fracture motion during compression loading indicated that closure of the fracture in the z direction would not likely exceed 10 mm with negligible anteroposterior displacement (y direction). This confirmed that, for fractures used in this study, maximum motion during torsion or compression loading occurred at the anterior of the fractured vertebra. Based on primary motion occurring in the frontal plane of the anterior vertebral body during compression and torsion tests, a biaxial displacement transducer with a range of 10 mm would provide fundamental results for evaluating the effectiveness of spinal fixation instrumentation in stabilizing fractures used in this study. A system of three biaxial transducers would meet an ultimate objective of three dimensional measurement if required. This system is shown in Figure 5.10.

5.4. The Transducer

A displacement transducer meeting the design criteria was designed and fabricated. Purchasing extensometers (strain clips) used by others [67, 79] or multi-faceted two and three dimensional displacement transducers was rejected due to cost, lack of range, excessive stiffness or mounting difficulty at the anterior body in combination with existing global rings.

The basic features of the transducer are shown in Figure 5.4. The aluminum transducer frame mounts on a ring used with the previous

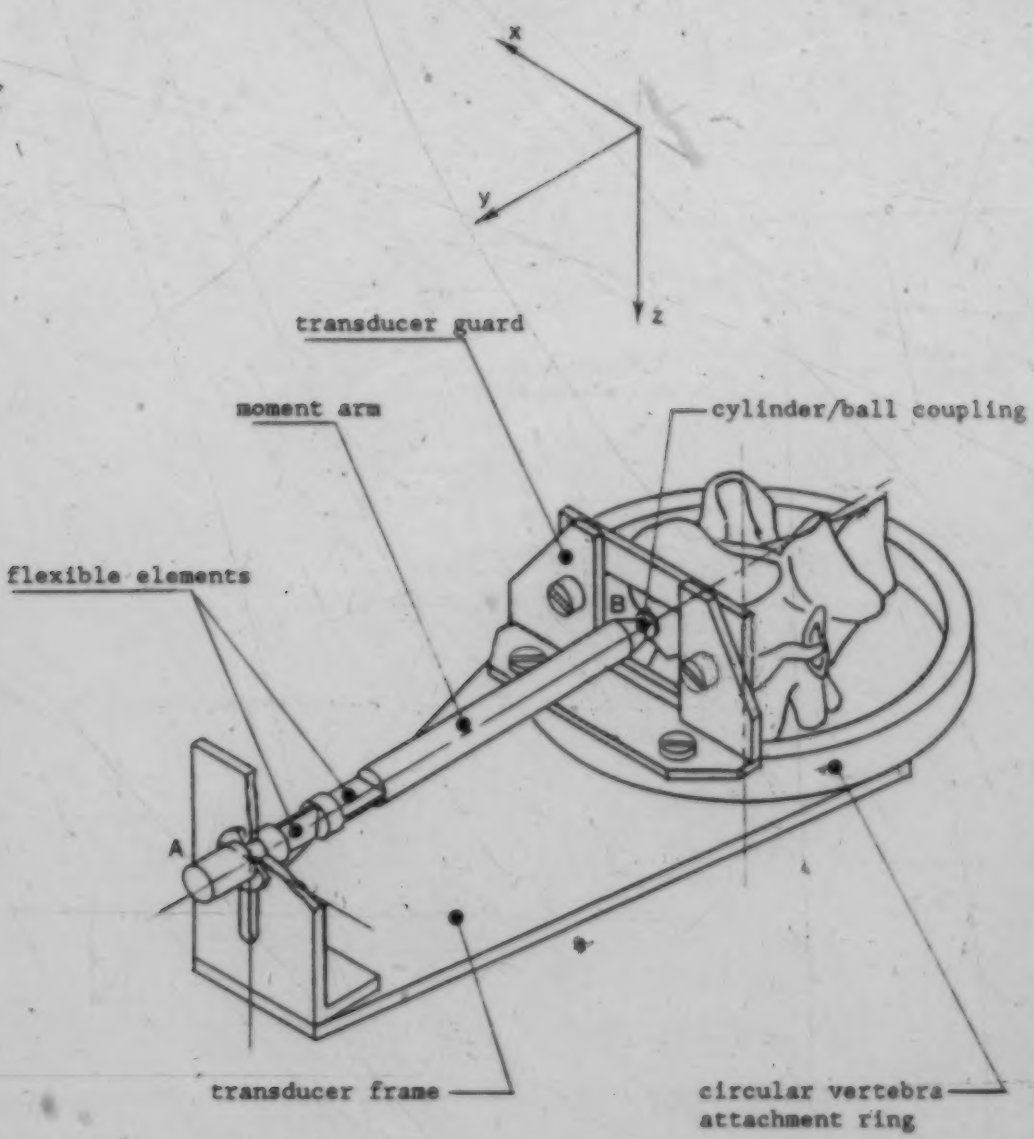


FIGURE 5.4. BIAXIAL TRANSDUCER MOUNTED ON PORCINE VERTEBRA WITH WEDGE DEFECT

global method and adjusts the transducer position in the A/P (y) direction. The ring is attached to the inferior portion of the fractured vertebra with pointed radial screws such that fracture movement is not restricted. An upright attachment at the outer end (A) of the frame allows for transducer adjustment in the x and z directions. Mounted to the upright is the measurement transducer comprising a cantilever beam with two flexible elements set perpendicular to each other. One flexible beam element is sensitive to displacements of the socket end (B), attached to the vertebral body in the z direction (vertical); the other is sensitive to displacement in the x-direction (horizontal). Four strain gauges are attached to each element and are incorporated in a four active arm wheatstone bridge. The steel flexible beam elements and aluminium moment arm comprising the cylindrical coupling are press fitted in an integral unit shown in Figure 5.5. Material specifications are listed in Table 5.1. Design calculations for the flexible element and moment arm are detailed in the appendix. The internal cylindrical surface of the moment arm fits over a 3.81 mm diameter ball coupling mounted in the superior component of the fractured vertebra. The stem of the ball is fitted into a hole in the vertebra. A clearance of 0.008 mm between the ball diameter and the inner diameter of the rod allows the ball to slide freely along the moment bar (y direction). The limit guard is attached to the transducer frame to protect the transducer from overextension and damage in case the fracture displacement exceeds the limit of the transducer. Tests showed that further application of force at the guard would bend the ball stem at the vertebra until the ball dislodged from the coupling with no damage to the flexible elements. The complete

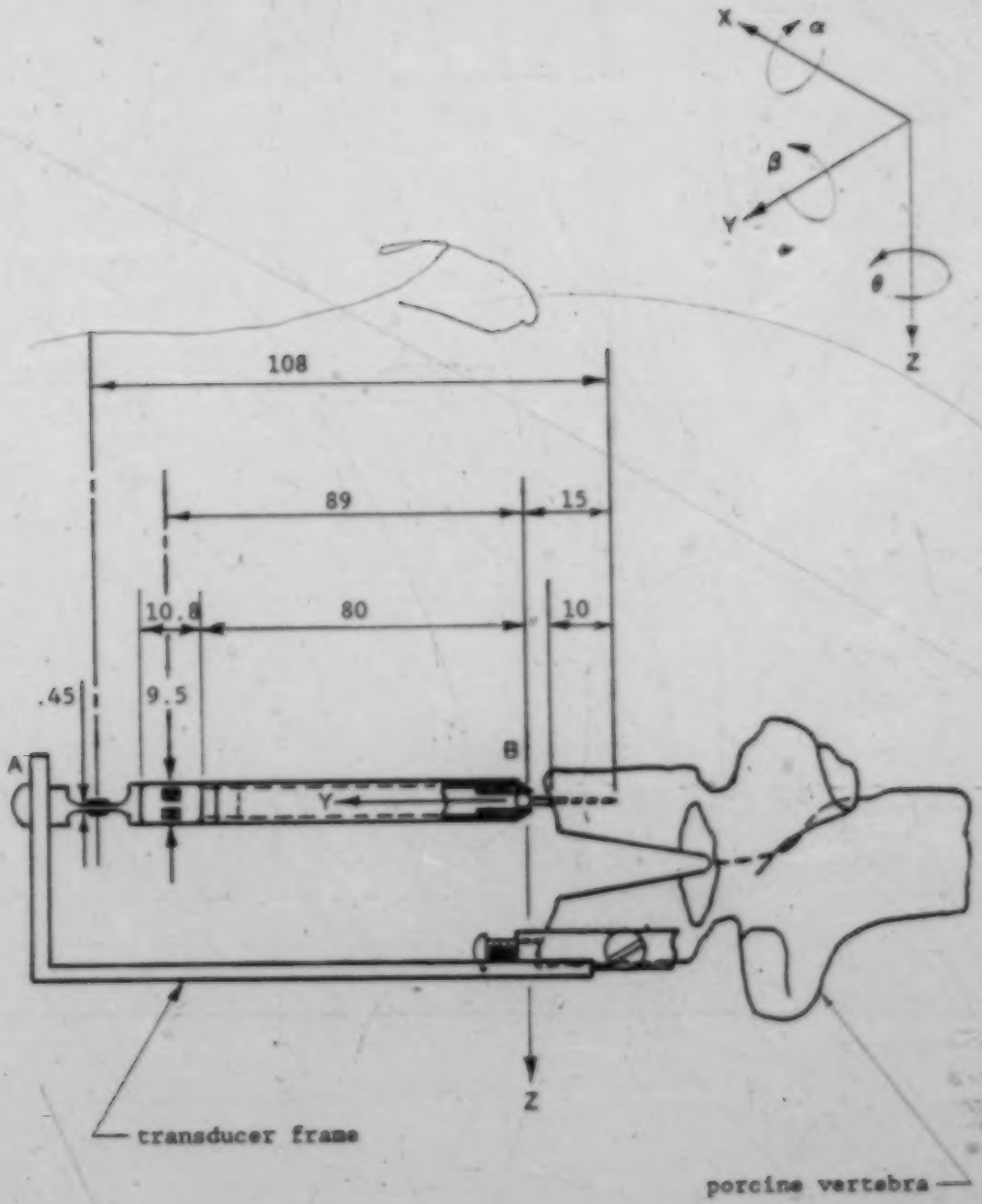


FIGURE 5.5. TRANSDUCER DETAILS (all dimensions in millimeters)

TABLE 5.1. TRANSDUCER MATERIAL SPECIFICATIONS

Beam Elements:

Material	AISI W1 tool steel (annealed)
Tensile Strength	703 MPa
Yield Strength	572 MPa
Hardness	385 Rockwell D

Moment Arm:

Material	6061 T6 aluminium
Tensile Strength	310 MPa
Yield Strength	276 MPa

TABLE 5.2. TRANSDUCER CALIBRATION AND SPECIFICATIONS

	z direction 108 mm moment arm	x direction 89 mm moment arm
Design Range	10 mm (+/- 5 mm)	10 mm (+/- 5 mm)
normal stress	199 MPa	243 MPa
Calibration Range	20 mm (+/- 10 mm)	15 mm (+/- 7.5 mm)
normal stress	397 MPa	364 MPa
accuracy	+/- 0.04 mm	+/- 0.04 mm
Stiffness	0.077 N/mm	0.110 N/mm

transducer assembly weighs 2.99 N.

5.5. Transducer Calibration

Transducer calibration results are shown in Table 5.2. Transducer stiffness was determined by mounting the transducer horizontally and attaching dead weights to an adapter inserted into the cylindical end of the transducer and measuring deflection. The maximum reactive load generated over the z and x design range of +/- 5 mm was .3585 N and .549 N respectively.

Strain analysis following initial displacement calibration over the 10 mm design range allowed the maximum range to be doubled for the 108 mm arm and increased 1.5 times for the 89 mm arm with a minimum safety factor of 1.44. Calibration was then repeated in the x direction over a range of 15 mm and in the y direction to 20 mm. The limit guard restricted transducer displacement during normal testing to 10 mm.

The ball was mounted on a bi-directional micrometer stage with adjustment increments of 0.025 mm (0.0001 in). The transducer cantilever beam was mounted overhead in a drill chuck such that the longitudinal axis of the transducer was vertical and the position of the bottom end of the transducer was controlled by the ball/micrometer stage configuration. Starting at the origin, the micrometer stage traversed a +/- 10 mm path in the z direction (keeping x-displacement at zero) then returning to the origin. Figure 5.6 shows uni-axial error in the z direction. The maximum error of 0.04 mm (0.2%) is due to hysteresis and non-linear bending effects of the flexible elements. The primary interaction error of 0.05 mm in the x direction due to a displacement in z (Figure 5.7) is a result of misalignment since error

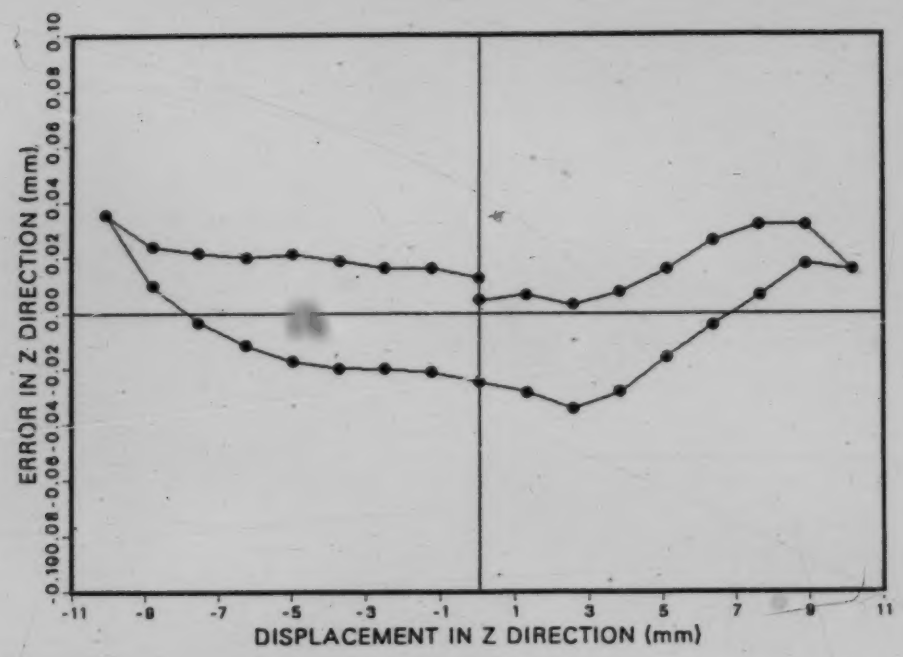


FIGURE 5.6. UNIAXIAL ERROR IN Z DIRECTION

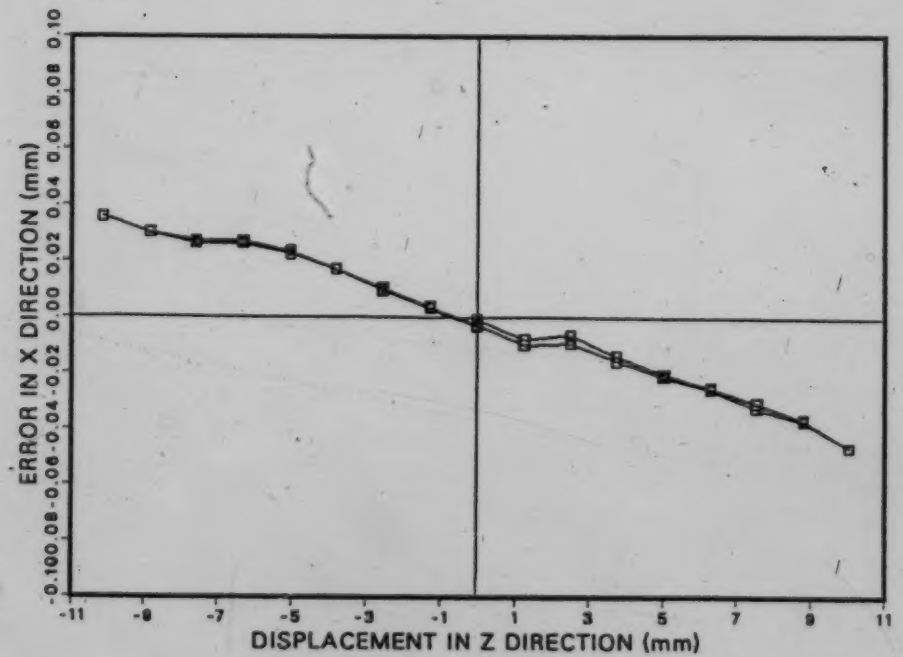


FIGURE 5.7. X DIRECTION ERROR DURING Z DISPLACEMENT

is virtually linear. Difficulty of alignment of transducer cells with the displacement axis proved to be the most significant source of error. The small inflection point near the origin was due to the clearance of 0.008 mm over the ball connection. Figures 5.8 and 5.9 demonstrate similar calibration results for displacement in the x-direction over a range of +/- 7.5 mm.

When both z and x displacements were at their maximum values of +/- 10 mm and +\- 7.5 mm respectively, interaction errors were 0.25 mm and 0.20 mm respectively and were not considered significant. For the types of spine tests in this investigation, x and z displacments do not both approach maximum values simultaneously in the same tests.

5.6. Data Acquisition

A microcomputer with an analog to digital data acquisition system provided a resolution of 5 mv/bit and sampled displacement data from transducer channels comprising two Wheatstone bridge units and the loading device. The maximum voltage range was set at +/- 10 volts for each channel. For calibration purposes, a range of 20 mm produced a resolution of 0.005 mm/bit. This was reduced to 0.0025 mm/bit over the normal range of 10 mm experienced during testing. Noise through the Wheatstone bridge unit was found to be 5 mv giving a combined resolution of .01 mm/bit for calibration and .0075 mm/bit for testing. The data acquisition system sampled data at rates of 0.2 Hz and 1.0 Hz for monotonic loading. Sampling frequencies up to 5 Hz is possible. On-line data acquisition provides immediate processing of data and output of results as well as potential for feedback control of the experiment

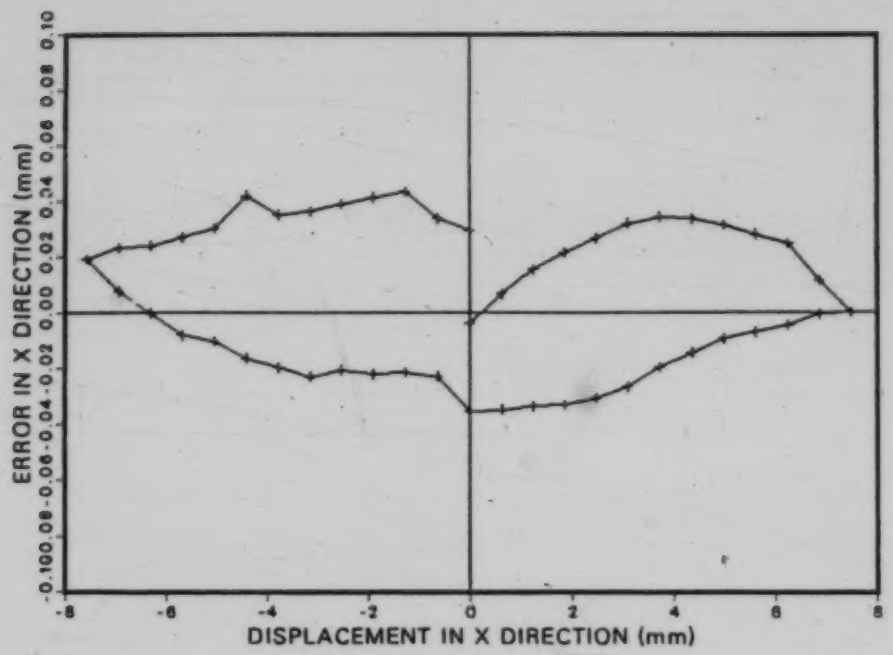


FIGURE 5.8. UNIAXIAL ERROR IN X DIRECTION

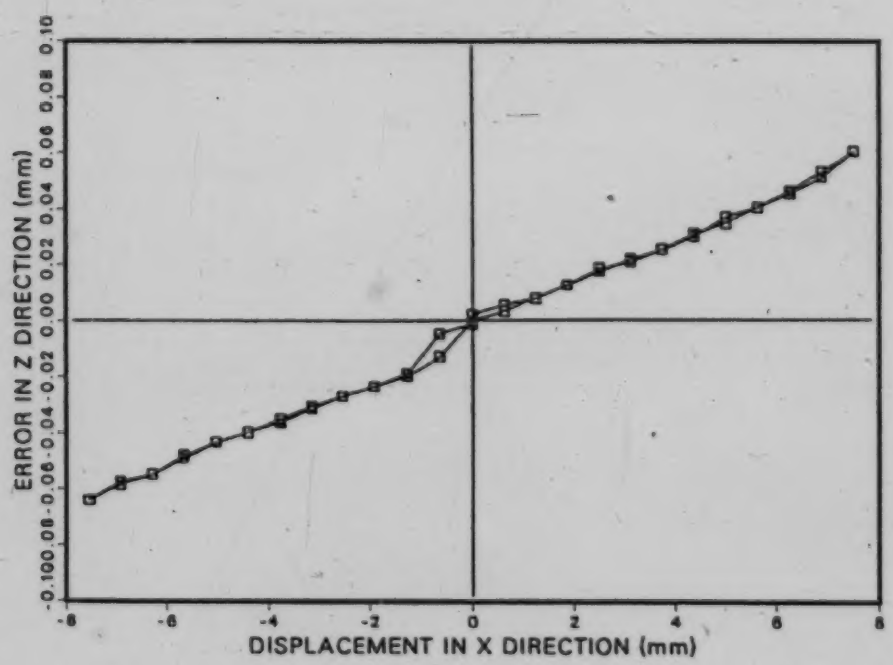


FIGURE 5.9. Z DIRECTION ERROR DURING X DISPLACEMENT

where a predetermined maximum allowable displacement at the fracture site would limit loading. A limit to fracture site motion would prevent further damage to the spine. A two tier limit system could be a feature of a repetitive or cyclic loading experiment where physiological load and fracture site displacement limits are introduced to ensure experimental control is maintained.

5.7. Testing the Transducer - Comparison with Global Measurement System

A series of tests was performed with combined local and global measurement of fracture site motion as shown in Figure 5.10. The local photographic cross-hair technique was also employed as a reference in case of discrepancies between the two measurement systems. These measurement systems were applied jointly to a seven segment porcine spine instrumented with Harrington compression rods and subjected to compression and torsion tests.

A global measurement system quantifies three displacements and three rotations at the center of the measurement system (marker ring)- included in this is digitizing error. Collected data does not allow direct comparison of results from global and local measurement systems. To estimate the maximum fracture site motion the center of rotation must be determined from the data. Extrapolation is used to determine the largest relative displacement for the fractured and normal segments shown in Figure 5.1. The difference between the displacements of the normal and fractured segments is the estimated displacement between fracture surfaces. Researchers who use global systems have not done this because the process is tedious and inherently inaccurate.

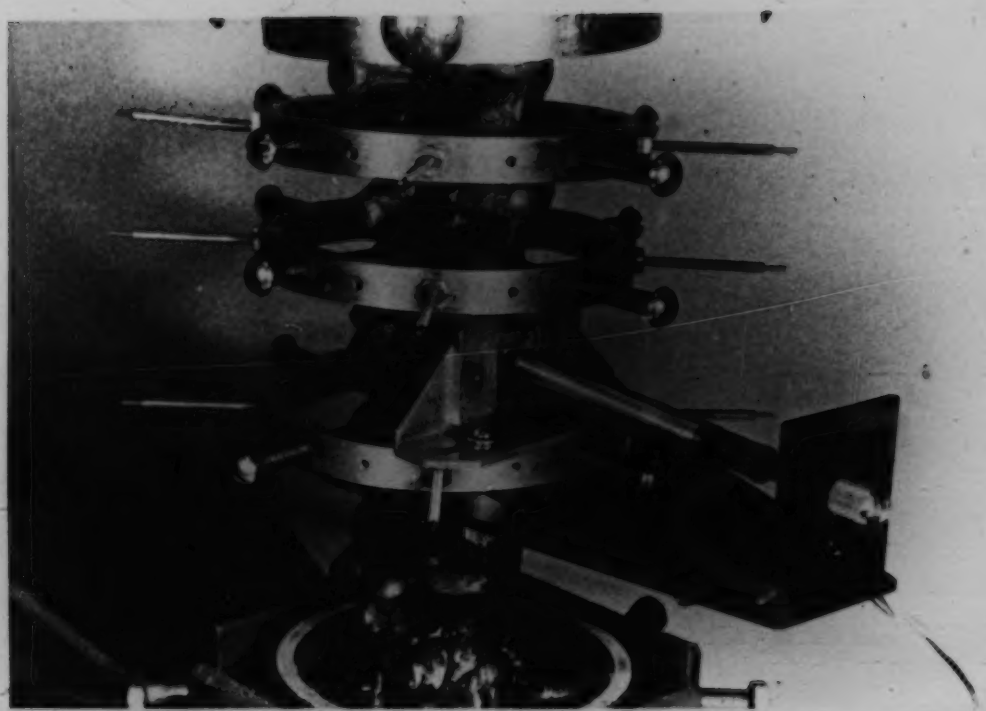


FIGURE 5.10. INSTALLATION OF GLOBAL AND LOCAL MEASUREMENT SYSTEMS

5.7.1. Compression Test

The porcine specimen was loaded with a 4000 N axial compression load (exceeding physiological loading) to ensure significant fracture site motion. Digitized results (Figure 5.11) showed vertical motion at the center of the marker rings of the normal and fractured sections to be 1 mm and 2.5 mm respectively. The difference of 1.5 mm is attributed to fracture collapse. Digitized rotation about the x-axis (alpha) is shown in Figure 5.12. Using the results of Figures 5.11 and 5.12 combined with the distance from an approximated center of rotation about the x-axis to the anterior body allows an estimate of fracture closure at the anterior body to be made (Figure 5.13). This allowed a direct comparison with on-line transducer results shown in Figure 5.14. Significant data scatter, normally observed with photographic methods, is not apparent in the transducer method. Cross hair references were not needed since both methods showed similiar results and anteroposterior translation was small compared with primary measurements.

5.7.2. Torsion Test Results

The same spinal specimen was subjected to torsional loading to a maximum of 9 Nm. Loads were measured incrementally with three minutes allowed between readings to allow for creep. (Incremental dead weight loading was replaced after this experiment with a hydraulic torsion actuator). Global digitized vertical displacement results of both normal and fractured segments shown in Figure 5.15 illustrate significant data scatter when compared to vertical transducer results in Figure 5.17. Digitized results of normal segment and fractured segment rotation about the z axis are shown in Figure 5.16. The digitized

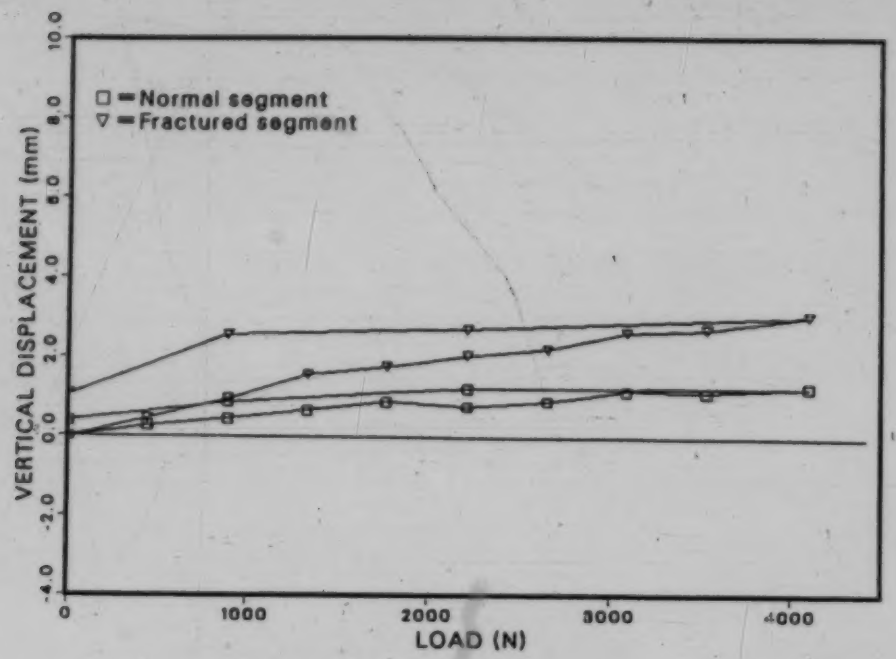


FIGURE 5.11. COMPRESSION TEST GLOBAL PHOTOGRAPHIC/DIGITIZED VERTICAL (z) DISPLACEMENT RESULTS AT CENTRE OF MARKER RINGS

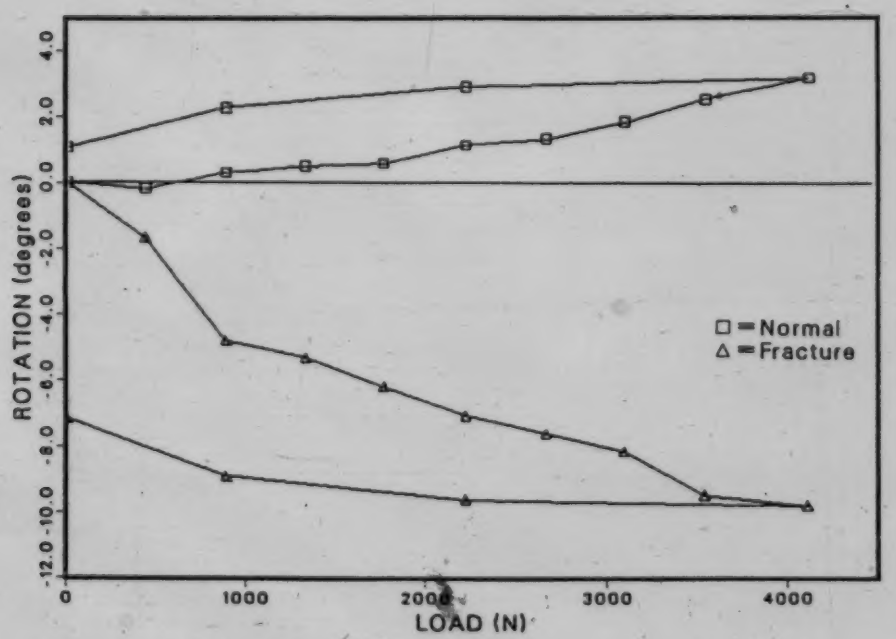


FIGURE 5.12. COMPRESSION TEST GLOBAL PHOTOGRAPHIC/DIGITIZED FLEXION ROTATION (α) RESULTS AT CENTRE OF MARKER RINGS

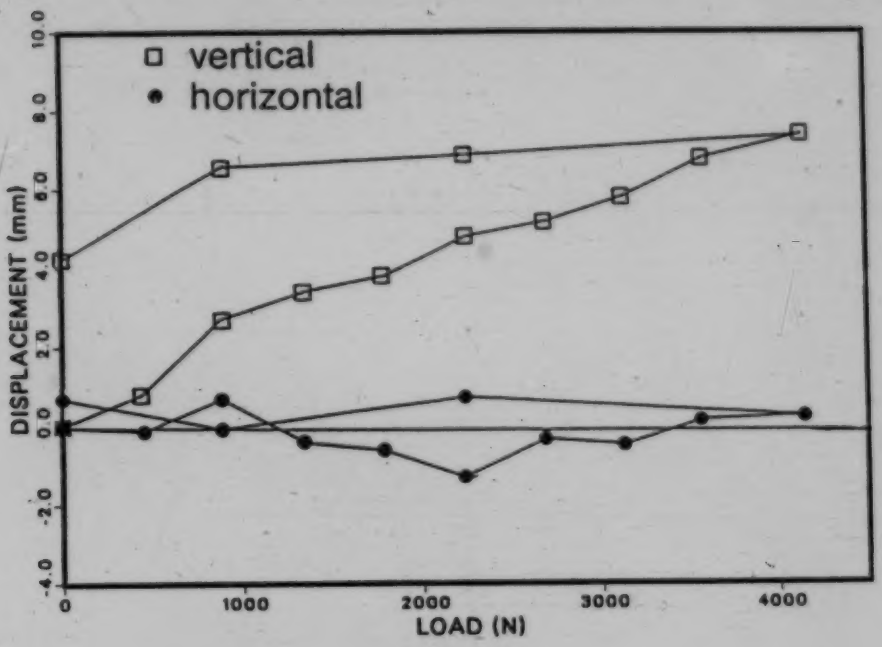


FIGURE 5.13. REDUCED GLOBAL PHOTOGRAPHIC/DIGITIZED RESULTS AT ANTERIOR VERTEBRAL BODY FOR COMPRESSION TEST

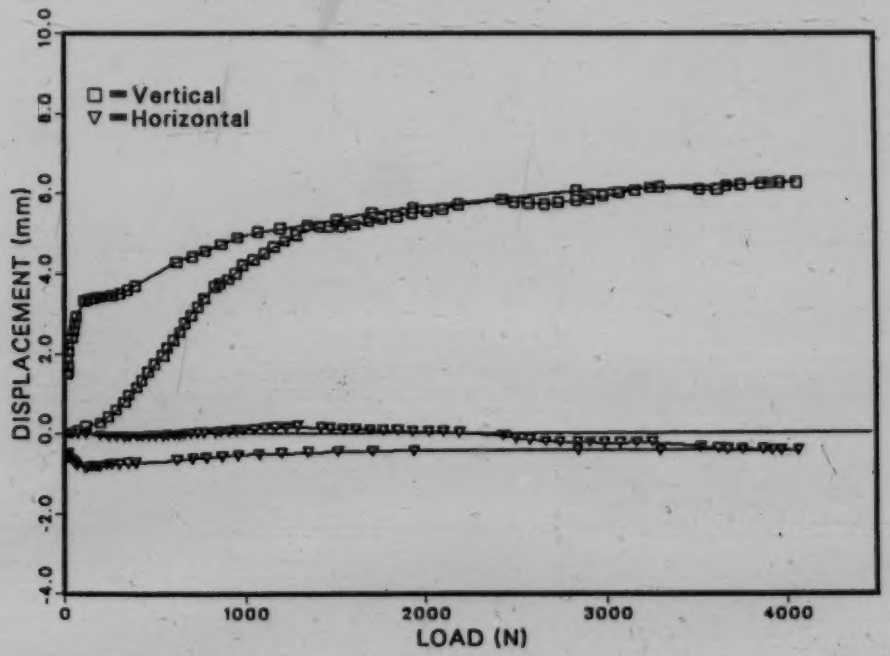


FIGURE 5.14. LOCAL TRANSDUCER MEASUREMENT OF DISPLACEMENT IN FRONTAL PLANE AT ANTERIOR VERTEBRA BODY DURING COMPRESSION TEST

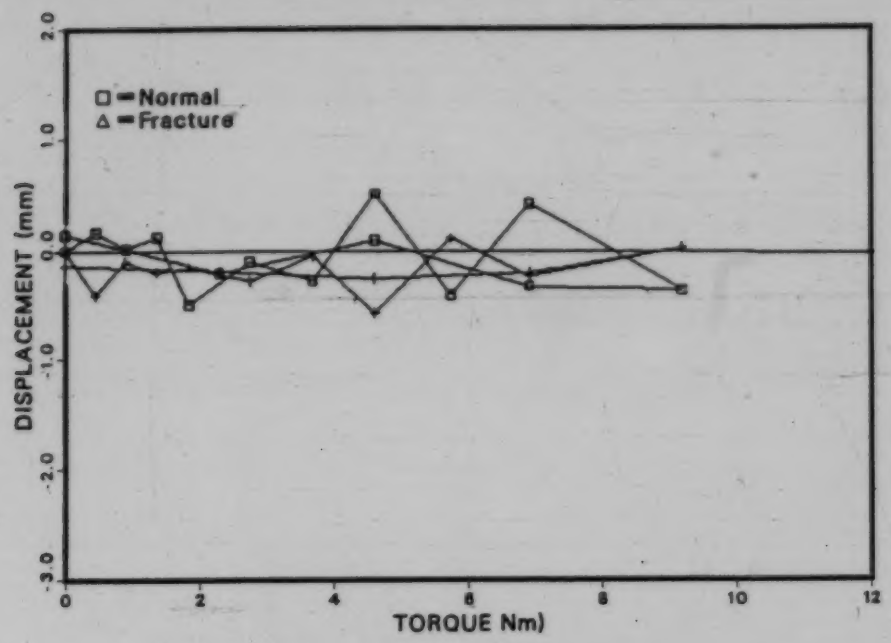


FIGURE 5.15. GLOBAL PHOTOGRAPHIC/DIGITIZED VERTICAL DISPLACEMENT DURING ROTATION TEST

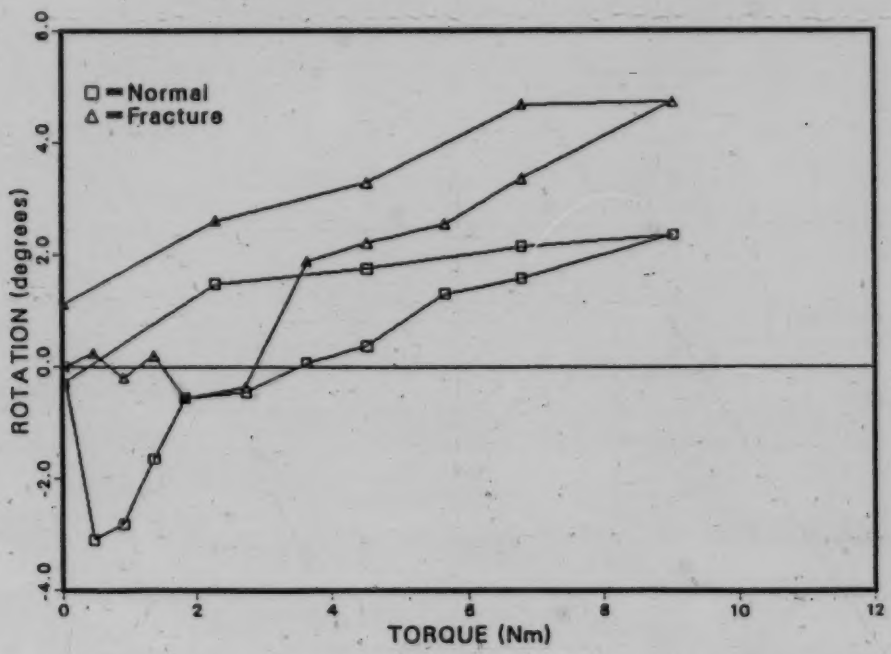


FIGURE 5.16. GLOBAL PHOTOGRAPHIC/DIGITIZED FLEXION ROTATION (θ) DURING ROTATION TEST

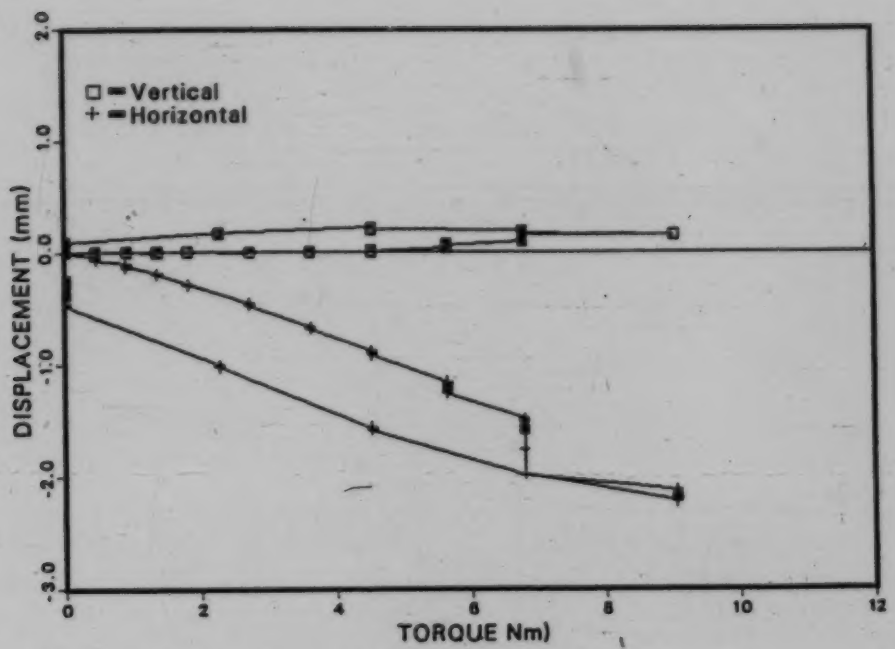


FIGURE 5.17. LOCAL TRANSDUCER MEASUREMENT RESULTS OF ROTATION TEST

results are not reduced to a form directly comparable to the transducer horizontal displacement results shown in Figure 5.17, but do illustrate how the significant rotational component is interpreted by the transducer as a significant translation representing a true measure of maximum fracture site motion.

5.8. Three Dimensional Measurement

The biaxial transducer is sufficient to acquire valid results for the fracture model considered in this study. Application of a system of three tranducers to achieve complete three dimensional analysis of fracture site motion for other fracture types is relatively simple. Once the characteristics of a particular fracture are determined a decision can be made as to whether three, two or one transducers are sufficient to achieve valid results. Figure 5.18 shows the three transducer system. In addition to the original transducer positioned at the anterior vertebra body are two transducers mounted opposite each other at adjacent transverse processes parallel to the lateral x axis and perpendicular to the antero/posterior y axis. Additional ball connectors are inserted in the region of the transverse processes on the superior portion of the fractured vertebra. The three transducer inputs are processed with results output on line. The transducer frame has a hinged portion which allows easy installation and removal from the instrumented spine. The three transducer system was used to evaluate pedicle screw stabilization [106] of the fracture type used in this study. The three dimensional results confirmed the most significant displacements occur in the frontal plane at the anterior vertebra body. Global displacement information can also be obtained

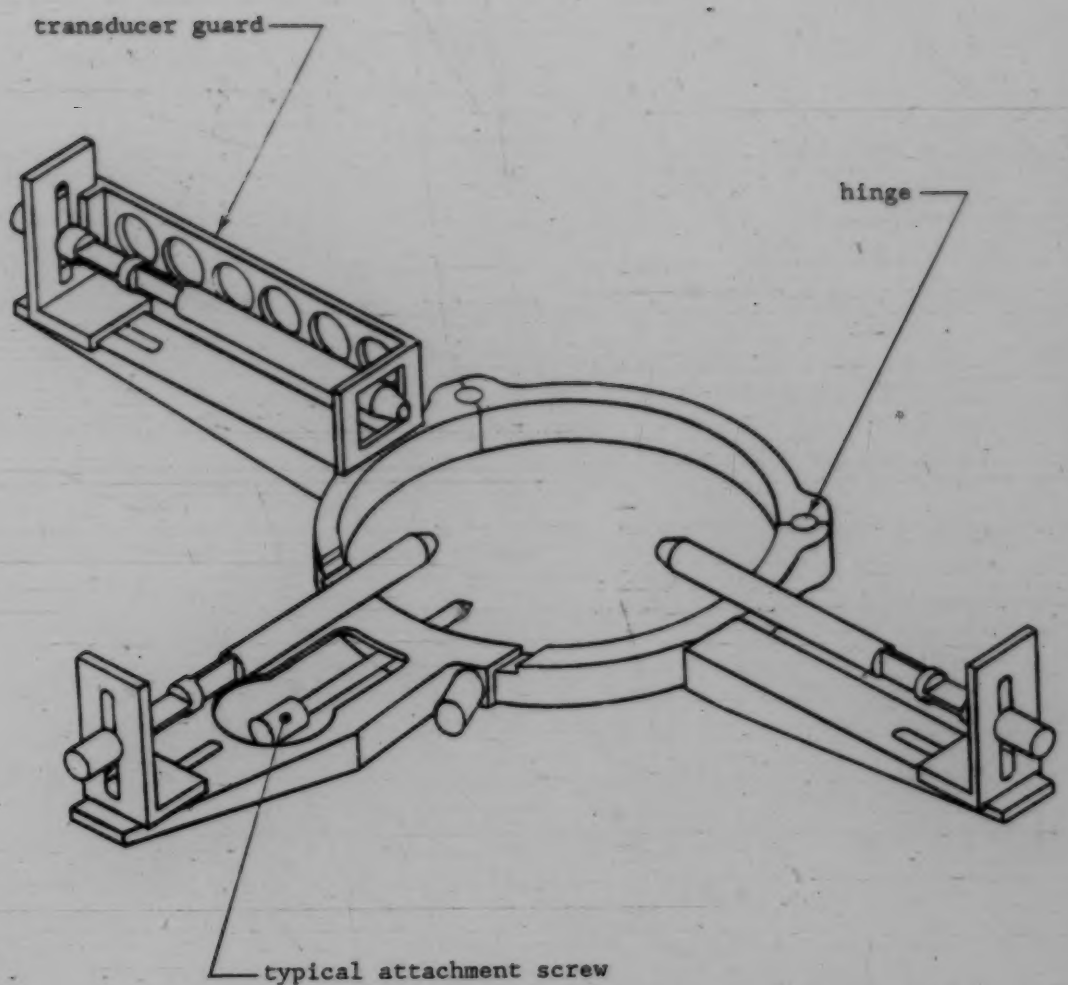


FIGURE 5.18. THREE TRANSDUCER SYSTEM FOR THREE DIMENSIONAL MEASUREMENT

with the three transducer system by measuring the relative displacement between vertebrae.

Chapter 6. Development of End Caps and Loading Fixtures

6.1. Problems With End Cap Designs

An end cap that assures rigorous control of the experiment is needed to obtain valid, repeatable experimental results. It is essential that load position and magnitude are known precisely and that effects of small variation in position can be determined. Other factors which bear on the quality of results include ease with which experiments can be performed and time required to conduct the tests so as to minimize tissue deterioration.

The purpose of an end cap and load fixture is to transmit force from the loading device to the spine in a reliable and repeatable manner. The end cap firmly attaches the end vertebra of a spinal test segment to fixtures designed to apply particular loads such as torsion, compression or compression bending. End caps commonly used at this time introduce many uncertainties into the test program.

Although scatter in experimental results can be partially attributed to variations in material properties, poor load control by the end caps is also a major cause of experimental error. Poor purchase on the vertebra by the end cap is a feature of existing designs.

Fixator screws [101], used in the previous end caps, [109, 78] permit elastic flexibility as well as motion within the allowances of threaded connections. Removal of soft tissue at the end vertebra is not necessary as pointed screws penetrate to the vertebral bone, however, penetration of soft tissue conceals poorly seated screws which may slip during loading. Radial arrangement of the screws makes accurate determination of load position difficult. This uncertainty is

enhanced by deterioration of these threaded devices with use. Many investigators attach to multiple vertebrae to improve purchase, however unwanted coupling effects may be incorporated; longer specimens are more difficult to control experimentally. Position and orientation upon removal and replacements of caps (on the same specimen) is not reproducible as no standard load fix point exists.

End caps which insert pins or rods into the end vertebrae [68, 5, 15] provide an accurate means of loading but are subject to bone yielding at the bone/metal interface jeopardizing the structural integrity of the bone. Complexities which add unnecessarily to the total time required to conduct tests inevitably add to the cost of the program and permit deterioration of tissue. For example, in the encapsulation method, thorough removal of soft tissue, exact preparation of both the bone surface and the potting material as well as the curing time delay the test itself. The exotherm which occurs from curing of acrylic [67, 80, 84, 8]; or a potting metal [90, 7]; causes tissue damage directly. Markolf [5] noted that heat generated from epoxy or polyester resin resulted in molds that were too hot to handle. Waiting for the molds to cool lengthens the time required to conduct experiments while using less catalyst results in excessive setting time permitting further dehydration. Soft tissue adjacent to the encapsulating material permits relative motion between the spine and the end cap. All encapsulating end caps incorporate at least one intervening unsupported disc between end cap and the first fixated vertebra. By including an extra disc a very flexible motion segment becomes a feature of the test. This leads to poor control of end conditions, different from in-vivo behavior. For in-vivo loading, muscle forces

restrict motion rather than allowing motion segments to flex along the path of least resistance. It should be noted that Luque rod testing by Wegner [69] resulted in soft tissue failure immediately above the fixated level suggesting poor control of end conditions and loading an unsupported disc.

6.2. End Cap Requirements

Physiological loading of instrumented spines includes torsion, compression and flexion, applied separately or in combination. In some programs, specimens are re-used for changes of load type or instrumentation. The end cap must permit precise changes of moment arm, load type and exact re-application of the same load. These requirements are not accomplished easily with existing end cap designs.

The end cap must achieve firm purchase on the vertebra and be applied easily and quickly to minimize deterioration of and damage to the spine. Soft tissue removal should be minimized to reduce preparation time and to ensure maximum protection from dehydration. The end cap must attach to the end vertebra of a segment fixed with any type of instrumentation such as rods or pedicle screws without interference between the end cap and the instrumentation. The end cap should facilitate testing without intervening discs. It should be removable and reusable for repeated testing; it is important to be able to reposition the end cap precisely on the vertebra. Accurate determination of load position with respect to a reference point on the vertebra is essential. The end cap must be capable of transmitting compression, bending and torsion loads separately or in combination. It should be light to avoid damage to the spine during handling.

6.3. End Cap Design

The end cap has two separate components: the vertebra attachment component which attaches directly to the vertebra and the load application/positioning unit which is secured to the vertebra attachment component and allows all the essential types of load to be applied to the vertebra (Figure 6.1).

Based on measurements of the size and proportions of porcine vertebrae it was evident that these vertebrae were sufficiently robust to obtain a secure purchase for the transmission of physiological loads to the spinal column. The end cap was thus designed to attach to a single vertebra.

The centre of the body is often a load reference point [5, 15, 81, 18, 24]. However, locating the centre of the kidney shaped vertebral body in a repeatable manner is imprecise due to the variation in shape and size of vertebrae. The posterior wall of the vertebral body consists of cortical bone and parallels the longitudinal axis of the spinal canal. In this study, a standard load reference position was chosen at the junction of the sagittal plane with the posterior wall of the vertebral body (Figure 6.2, item A). Location of this is precise and unaffected by deformation of either the body or the posterior elements.

6.3.1. Vertebral Body Attachment Component

The new end cap produces sufficient force through two vises articulating on lead screws (Figure 6.2, item C). These vises clamp the posterior wall of the body (A) against the spinal canal pin (E) forcing

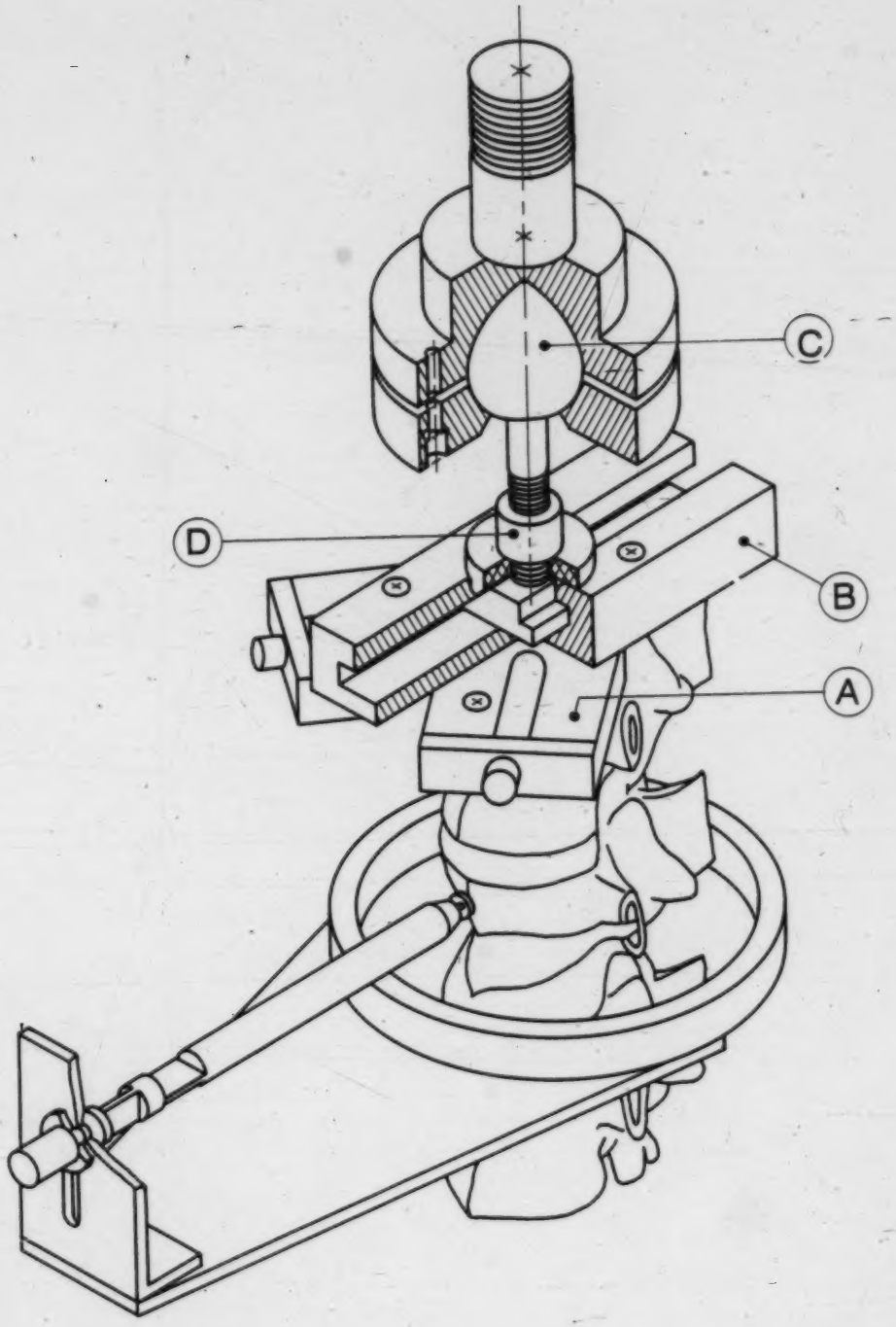


FIGURE 6.1. ENDCAP AND COMPRESSION LOADING FIXTURE

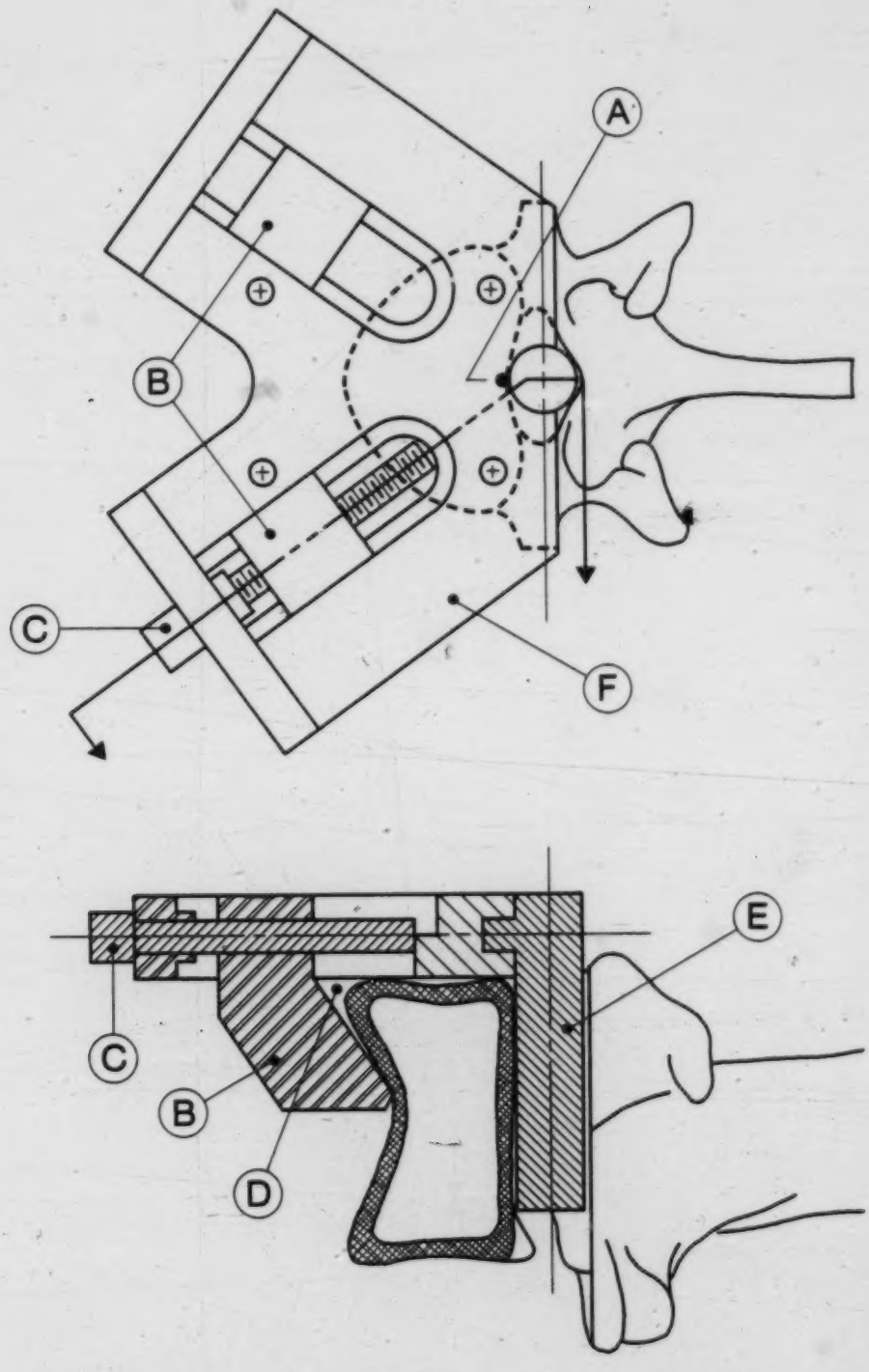


FIGURE 6.2. END CAP MOUNTING DETAIL

the pin and the spinal canal into alignment. The wedge shaped vises conform to the saddle like-curvature of the vertebral body. Clearance between the vise and the body near the vertebral end plate (D) ensures that the force is applied near the centre of the body and is primarily horizontal, securing the canal wall to the pin. The vertical component of force applied by the wedge ensures secure contact with the primary structural plate (F). The vises (B) are independently actuated to accommodate irregularities and deformities. The edges are rounded to reduce stress concentrations at points of contact or damage to the cortical wall of the vertebra.

An optional clip (Figure 6.3, part B) located at the spinous process, articulates in the anteroposterior direction and serves two functions. It provides precise location of the spinous process in the sagittal plane and resists slippage of the vertebra during torsion tests. The clip provides additional purchase but does not exert a force against the spinal canal pin as this would separate the pin from the anterior spinal canal wall.

The horseshoe shape of the spinous process locating plate allows long posterior fixation rods or plates to protrude beyond the end cap. The spinous process plate bolts to the primary structural plate, which provides attachment points for various load application/positioning units.

The first end cap was fabricated from stainless steel. After verification of its strength and performance, a second end cap was made of aluminum. Both spinous process locating plates were made of aluminum and all clamps were made of brass to avoid galling.

Loading fixtures were designed to transmit simulated "in-vivo"

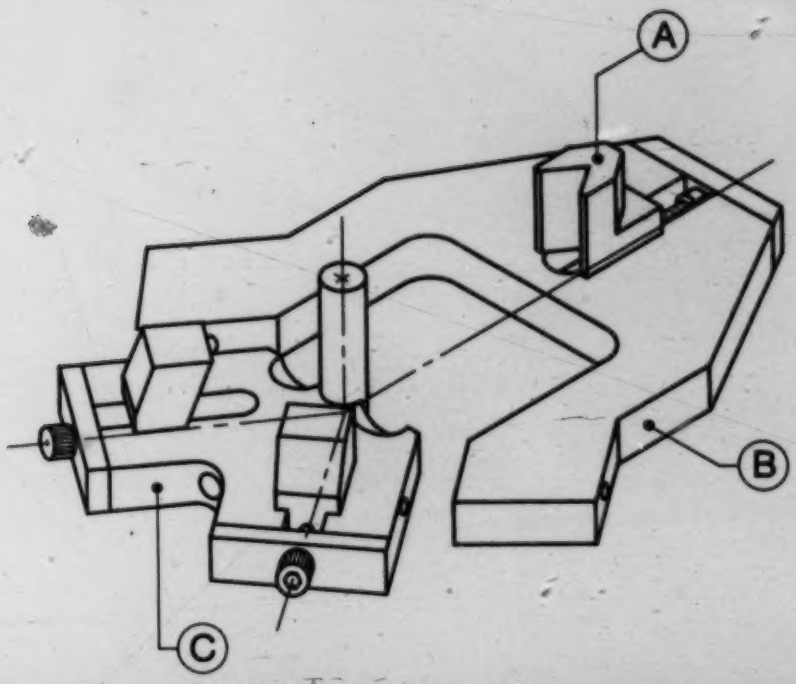


FIGURE 6.3. OVERVIEW OF END CAP

FIGURE 6.4. ATTACHMENT OF DISPLACEMENT TRANSDUCER TO END CAP

compression, compression bending and torsional loads. The fixture featured continuous positioning adjustments enabling precise control of the moment arm. Simple modification of this end cap permitted tests with human or animal spines.

6.3.2. Load Application/Positioning Unit

Specimen variations lead to differences in orientation of the end caps. The primary structural plates may not be parallel because of spinal curvature and are not necessarily perpendicular to the loading axis. For compression or compression bending tests, a ball/socket fixture shown (Figure 6.1) was designed to accommodate these differences. The ball/socket may be used in either a locked or free floating configuration, depending on the requirements of the experiment. Compression bending is accommodated with a clevis/pin attachment (not shown) which allows rotation about the bending axis. To date, tests have been based on lateral or anteroposterior bending. Accurate load positioning in the anteroposterior direction is provided by a T-slot plate (B). The ball/socket (C) is attached to the T-slot plate directly for axial compression, via a clevis/pin for bending and via a universal joint (not shown) for torsion loads. Location of the vertical load at any point in the horizontal plane is accomplished by stacking two T-slot plates at right angles.

6.4. Testing End Cap Purchase

The end caps were attached to an intact three vertebrae porcine specimen and loaded in compression and torsion. The specimen was overloaded to verify performance under severe conditions. The biaxial

displacement transducer was used to measure slippage of the vertebra with respect to the end cap. The transducer frame was secured to the end cap and the stem of a ball coupling was press fitted into the vertebral body between the vise clamps (Figure 6.4). For torsion tests, a dial gauge was mounted to measure the horizontal translation of the vertebra near the spinous process clamp. Five physiological 12 Nm torsional load cycles and two 33 Nm torsion cycles, approximately three times maximum physiological load, were applied in both directions. The end cap was subjected to a quasi-static axial compression load of 4450 N which is approximately twice physiologic loading (Nachemson, 1979).

Axial compression (Figure 6.5) caused a horizontal displacement (slippage) of 0.15 mm and a vertical displacement of approximately 0.3 mm during test cycle 1. During cycle 2, vertical motion (Figure 6.6) was less even though the end cap was not tightened prior to reloading. This indicated seating of the end cap occurred during the first cycle as only 0.05 mm vertical movement was detected during cycle 2. The vise clamps were retightened and the specimen retested. The motion during cycle 3 was the same as cycle 2 indicating that clamp tightening had no significant effect. Horizontal displacement results were similar.

The result of the first torsion cycle is shown in Figure 6.7. Vertical motion was negligible and the horizontal displacement was less than 0.04 mm for the complete cycle. The dial gauge indicated that no movement occurred at the spinous process. Motion from further repetitions is of the same order (Figure 6.8). Seating effects were not observed in the torsion test. The vise clamps were tightened after cycle 3.

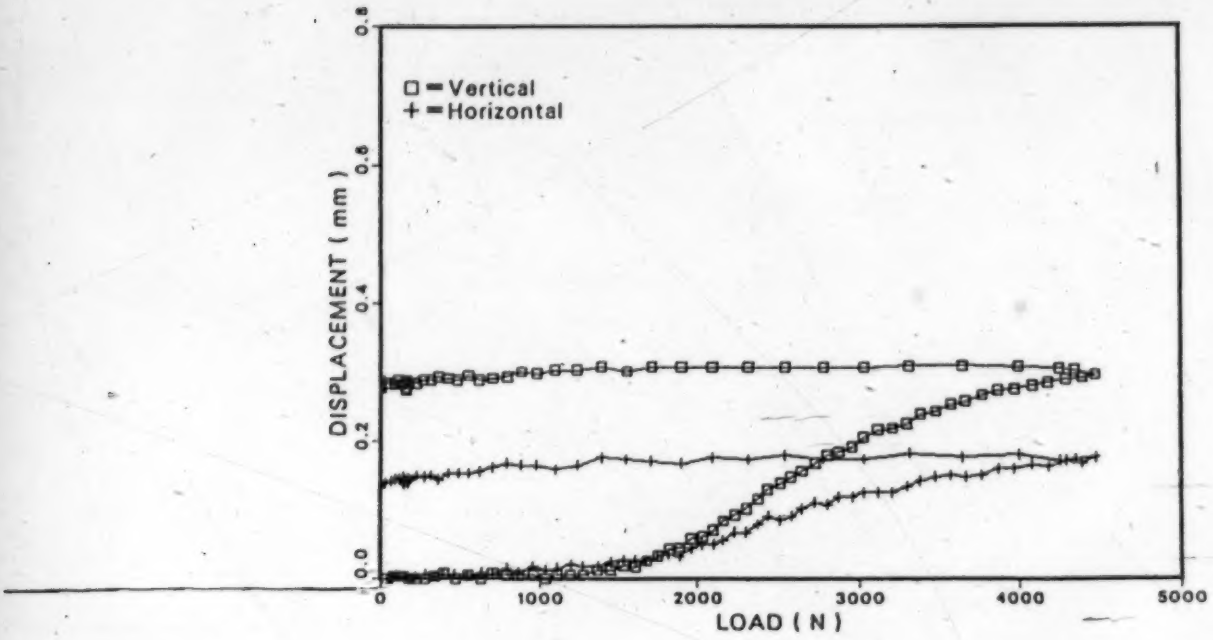


FIGURE 6.5. DISPLACEMENT OF VERTEBRA RELATIVE TO END CAP DURING A COMPRESSION TEST

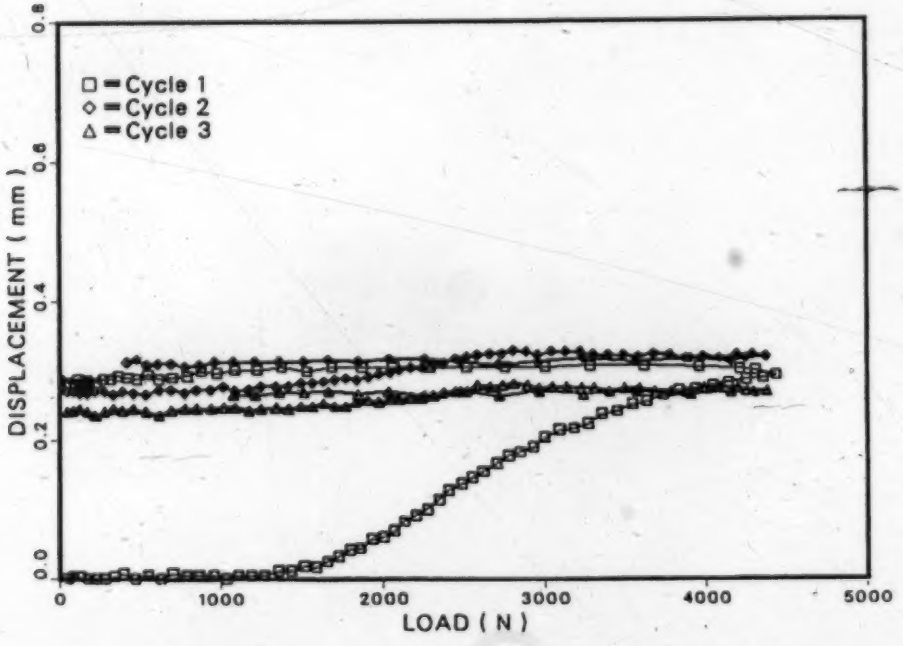


FIGURE 6.6. EFFECT OF REPETITIVE COMPRESSION LOADING ON RELATIVE END CAP MOVEMENT

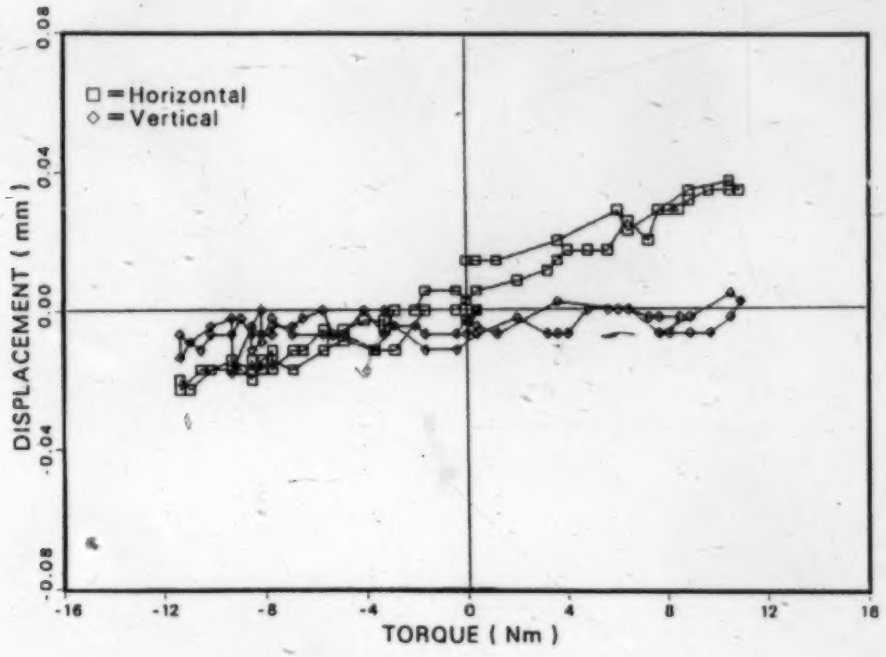


FIGURE 6.7. DISPLACEMENT OF VERTEBRA RELATIVE TO END CAP DURING A TORSION TEST (CYCLE 1)

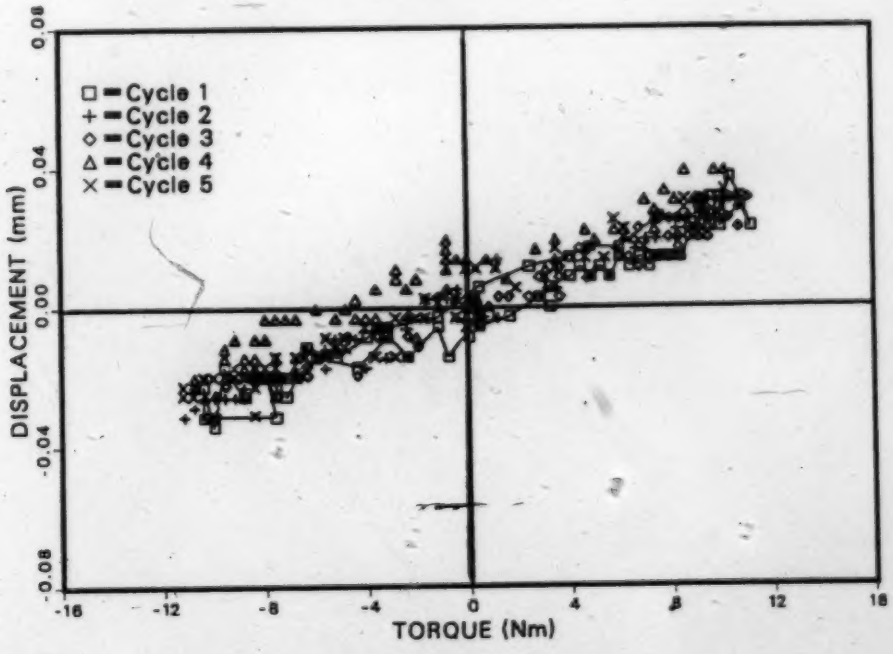


FIGURE 6.8. DISPLACEMENT OF VERTEBRA RELATIVE TO END CAP DURING A TORSION TEST (CYCLES 1-5)

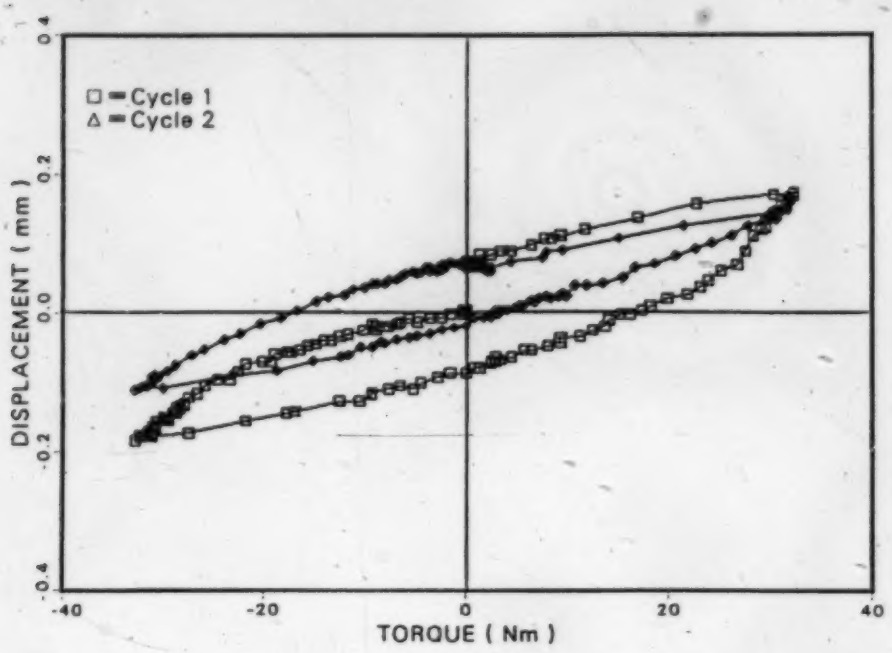


FIGURE 6.9. EFFECT OF TORSIONAL OVERLOAD ON END CAP PURCHASE

During cycle 1 of the torsion overload test (Figure 6.9) a maximum motion of 0.2 mm occurred at the clamps while none was recorded at the spinous process. Motion during cycle 2 was reduced significantly after tightening the clamps indicating that seating occurred.

Within physiological loading, removal and reattachment of the endcaps did not affect repeatability of the results.

6.5. Discussion of End Cap Test Results

The above results demonstrate the effectiveness of the end caps. The compression test showed seating of the end cap during the first cycle and negligible motion during subsequent cycles. Motion or seating effects occurred only during torsion overload tests.

The end cap is simple in design, time efficient in its attachment to the spine and provides rigid control of the end fixation points. It is a reliable load application unit and permits specific end conditions to be selected. The end caps and load fixtures allow secure mounting of a spinal test segment in an unstressed state for loading in either axial compression, compression bending or torsion. Preloading can be applied if desired. Location of the load is precise so that the magnitude of the bending moments is known accurately. The end cap significantly minimizes the effect of variables associated with in vitro testing of spinal fixation devises.

Chapter 7. Testing the System

A new method for evaluating the effectiveness of spinal fixation devices has been devised. Reproducible fracture creation, local fracture site measurement and loading end caps have been developed for evaluation of spinal fixation devices. The scope of this thesis includes checking all facets of the experimental system comprising specimen preparation, fracture creation, measurement transducer, end caps and loading fixtures. In vivo preload and test load conditions were carefully implemented. The standard clinically unstable compression/distraction fracture at the L2 vertebra level (described in Chapter 4) was produced in a three vertebra porcine segment. Although L1 is usually selected for fracture studies, the difference between L1 and L2 is considered negligible for testing purposes. Steffee posterior pedicle screw instrumentation was implanted with secure screw attachment through the lamina, pedicles and bodies of the L1 and L3 vertebra. The end caps were attached superior and inferior to the L1 and L3 vertebra respectively. The specimen was subjected to a sequence of physiological compression bending, axial compression and torsional load cycles in an attempt to emulate in vivo conditions.

Table 7.1 shows twenty-eight load cycles comprising nine initial compression bending load applications followed by seven axial compression loads, eight torsion loads and four final compression bending loads. All tests were performed after allowing a minimum of four minutes for recovery to occur between cycles and preloading as recommended by Panjabi [16]. The specimen was completely detached from the loading fixtures, end caps and measurement transducer prior to cycles

TABLE 7.1. TEST OF EXPERIMENTAL METHOD

Cycle	Preparation	Load Type	Load Range	Comments
1	install end caps and specimen	compression bending	0-135 N (0-9 Nm)	-little resistance to load as a result of excessive moment arm -excess fracture displacement
2	relaxation period zero load	compression bending	0-470 N (0-25.5 Nm)	-moved load position 25 mm more posterior
3	relaxation period zero load	compression bending	0-470 N (0-7 Nm)	-moved load position further 40 mm posterior
4	relaxation period zero load	compression bending	0-470 N (0 Nm)	-moved load 15 mm posterior -load at fulcrum -negligible bending moment
5	4 min. relaxation period zero load	compression bending	0-470 N (0-25.5 Nm)	-load application same as cycle 2 with 55 mm moment arm
6-7	4 min. relaxation period zero load	compression bending	0-470 N (0-25.5 Nm)	
8	removed and reinstalled end cap and transducer	compression bending	0-470 N (0-25.5 Nm	-similar to cyle 5
9	removed and reinstalled end caps and transducer	compression bending	0-470 N (0-25.5 Nm)	-reduction in load resistance and displacement
10	changed load fixtures preload to 700 N	axial compression	700-1900 N	
11-14	return to 700 N preload 4 min. relaxation period	axial compression	700-1900 N	
15-16	removed and reinstalled end caps and transducer	axial compression	700-1900 N	
17	changed load fixtures	torsion	+12 to -12 Nm	-lost data
18-19	4 min. relaxation period	torsion	+12 to -12 Nm	-lost data
20-21	4 min. relaxation period	torsion	+12 to -12 Nm	
22	4 min. relaxation period	torsion	+12 to -12 Nm	-overloaded to -17 Nm
23-24	removed and reinstalled end caps and transducer	torsion	+12 to -12 Nm	
25	changed load fixtures	compression bending	0-470 N (0-25.5 Nm)	-load response similar to cycle 5
26	4 min. relaxation period	compression bending	0-470 N (0-25.5 Nm)	
27	4 min. relaxation period	compression bending	0-470 N (0-25.5 Nm)	-lost data
28	4 min. relaxation period	compression bending	0-470 N (0-25.5 Nm)	

8, 9, 15, 16, 23 and 24 to determine reproducibility of the experimental system. In vivo loads were used as upper and lower limits (preload) during testing to prevent specimen damage.

7.1. Fracture Creation

Figures 7.1 and 7.2 show the load and displacement in the x and z directions (frontal plane of the vertebra) during fracture. Fracture (point A) occurred at a load of 2300 N (515 lb) producing a vertebral collapse (vertical displacement) of 4.2 mm during loading. The vertebra collapsed a further 0.8 mm before the cross-head was reversed or raised (point B). Horizontal displacement was negligible. The fracture closure recovered to approximately 2.5 mm when the load was removed, indicating some remaining elasticity due to intact tissue.

From Figure 7.1 it is apparent that a reduction in load resistance occurred at approximately 1000 N (point C). This may be due to load fixture seating or fracture at a vertebral end plate. This is verified in Figure 7.2 which shows no corresponding fracture displacement at the defect (although not done in this case, excess vertebral material should isolate the desired experimental segment from the fracture loading fixture to avoid damage; the excess material is resected prior to laboratory testing). The fracture load and displacements were similiar to previous multiple vertebra fractures, indicating the desired fracture was reproduced. The frozen vertebra fractured through the pedicles, lamina and spinous process (fracture was confirmed by X-ray which also showed a degree of calcification in one facet joint).

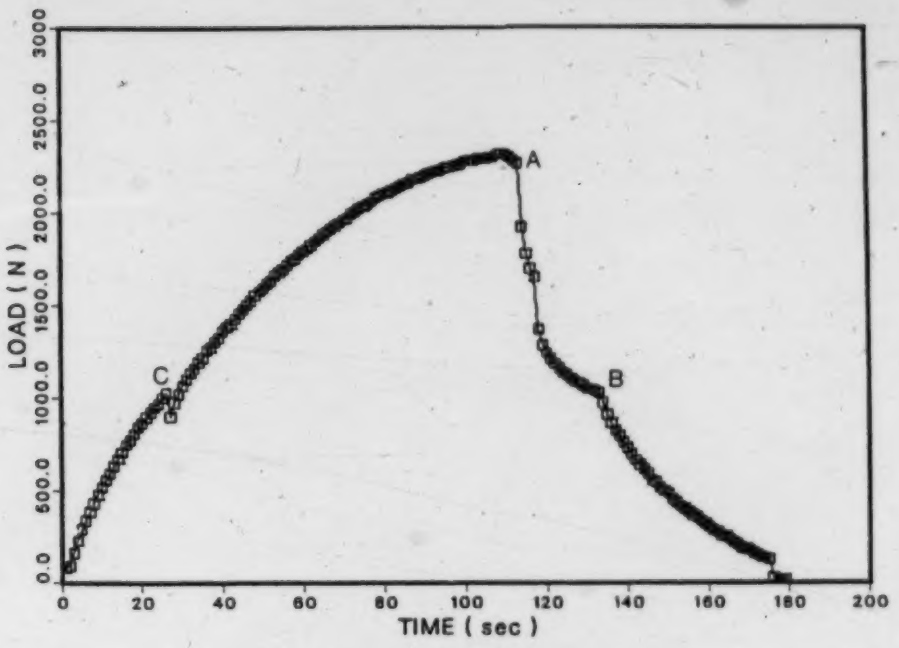


FIGURE 7.1. COMPRESSION LOADING DURING FRACTURE CREATION

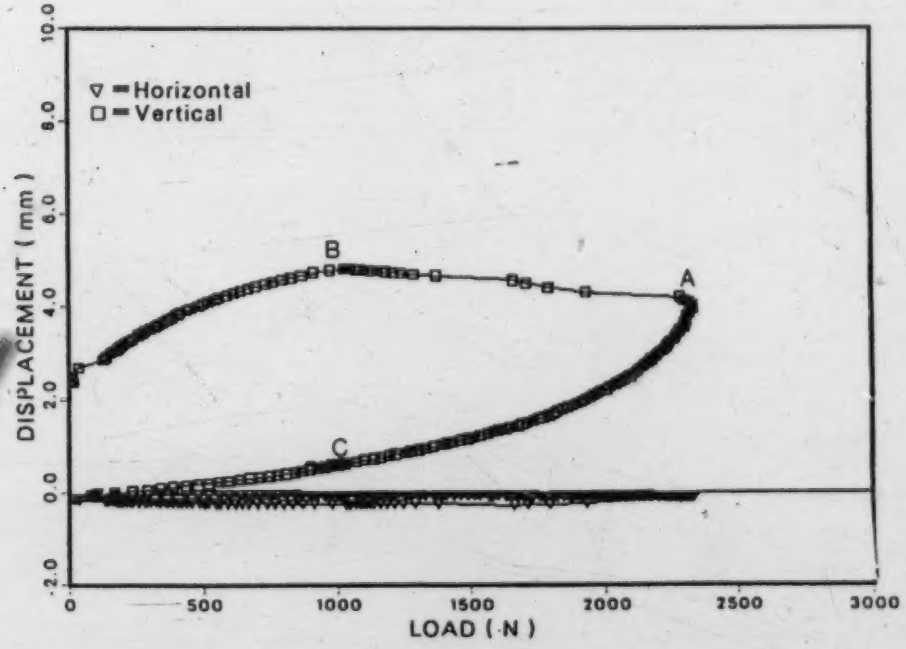


FIGURE 7.2. VERTEBRAL DISPLACEMENT DURING FRACTURE CREATION

7.2. Initial Compression Bending Test (cycles 1 to 9)

The first four compression bending cycles were dedicated to locating the fulcrum in the fractured vertebra (fixated with Steffee instrumentation) in order that the moment arm could be specified for compression bending loads. A compression bending load of 11 Nm was initially chosen as the load limit based on Nachemson's work [8]. A load of 220 N applied 50 mm anterior of the center of L2 (Figure 7.3) would produce a physiological bending moment of 11 Nm about the center of the vertebral bodies. For the first load application (cycle 1), load-time and load-displacement curves are shown in Figures 7.4 and 7.5 respectively. The maximum resistance to load at full fracture closure of 5 mm was only 130 N, far below the intended maximum of 220 N. The reason for the lack of load resistance was the defect and fracture resulted in a fulcrum much more posterior than the center of the vertebral bodies. This fulcrum had to be determined to estimate the bending loads in the fixated specimen. The 470 N load position was moved to a more posterior position (Figure 7.3) for each of the following three load cycles (Figures 7.6 and 7.7) for the purpose of locating the fulcrum in the fractured vertebra. The load position was moved 25 mm posteriorly for cycle 2 such that the load centerline was 15 mm anterior of the transverse process (Figure 7.3). The load rate proved to be much higher than cycle 1 with a fracture displacement of 3 mm (Figure 7.6). The load position was moved posteriorly a further 40 mm in cycle 3 such that the load centerline was at the anterior edge of the spinous process. Increased load rate, load resistance and a maximum fracture closure of 1 mm resulted. For cycle 4, the load was moved a final 15 mm to the posterior. Figure 7.7 shows that during initial loading the

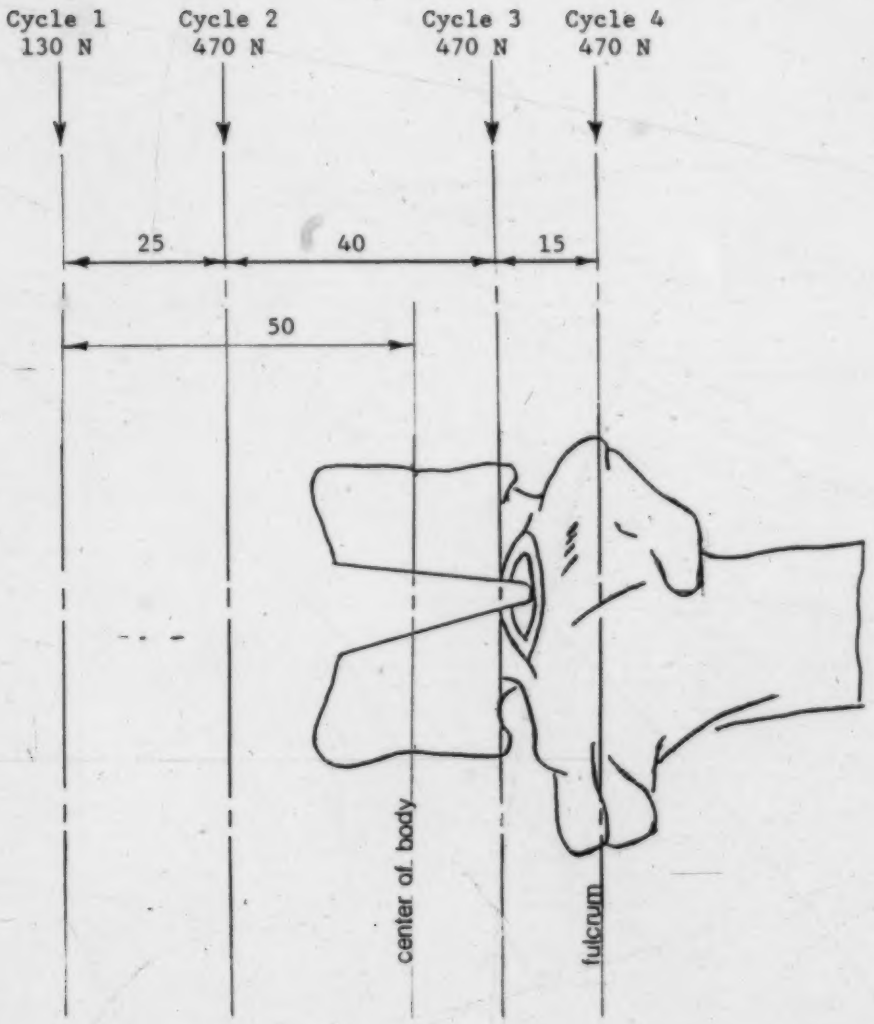


FIGURE 7.3. COMPRESSION BENDING TEST MOMENT ARMS (all dimensions in millimeters)

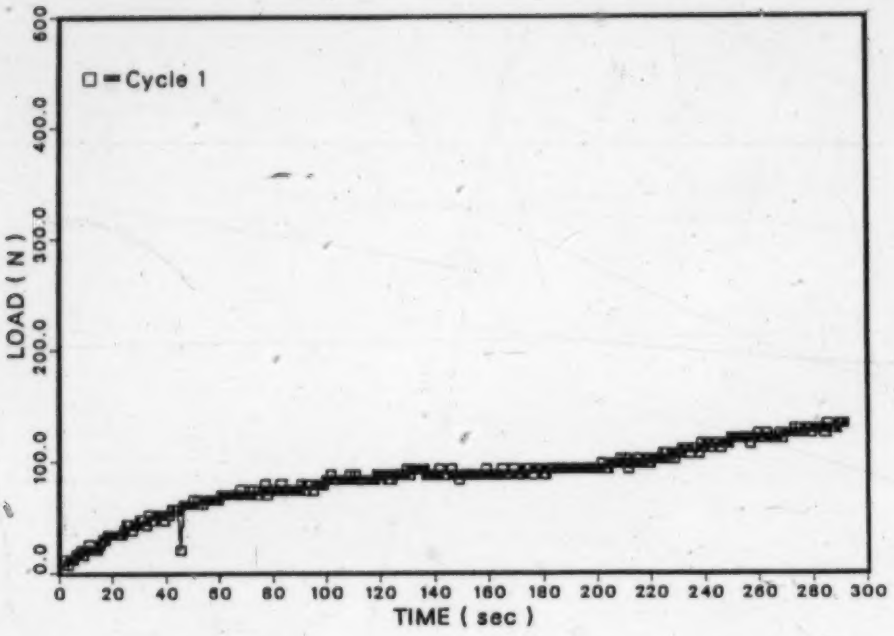


FIGURE 7.4. CYCLE 1 LOADING

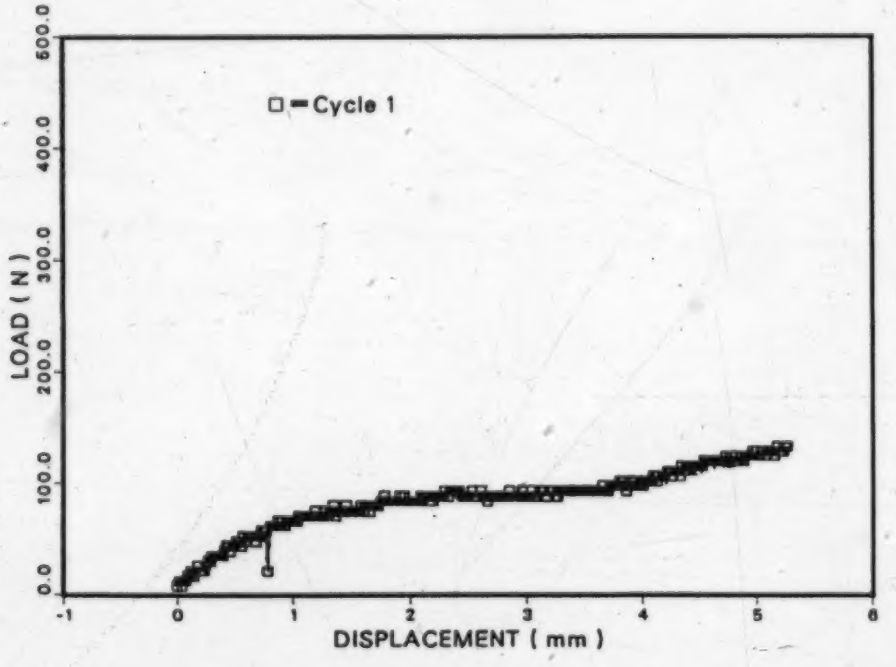


FIGURE 7.5. CYCLE 1 VERTICAL FRACTURE DISPLACEMENT

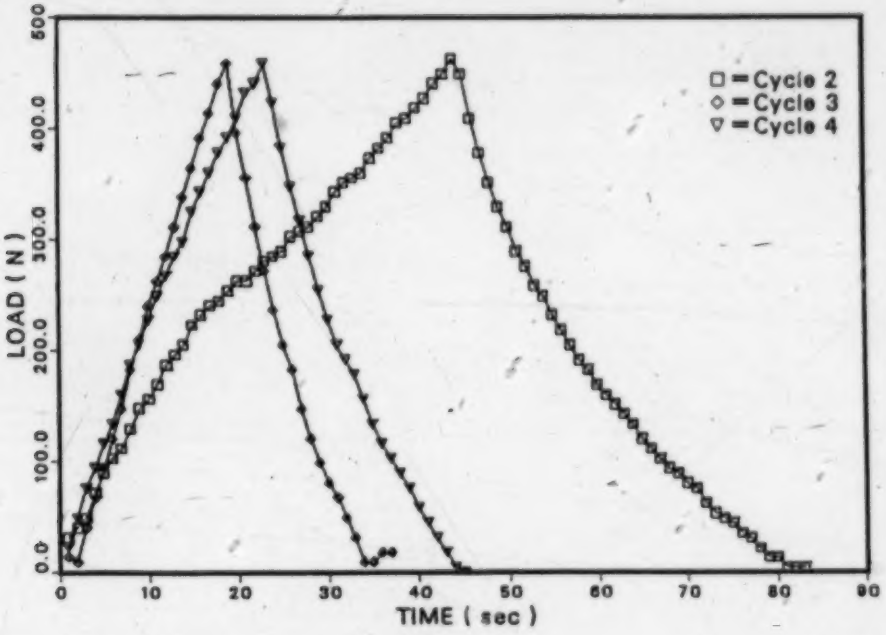


FIGURE 7.6. LOADING FOR CYCLES 2, 3 AND 4

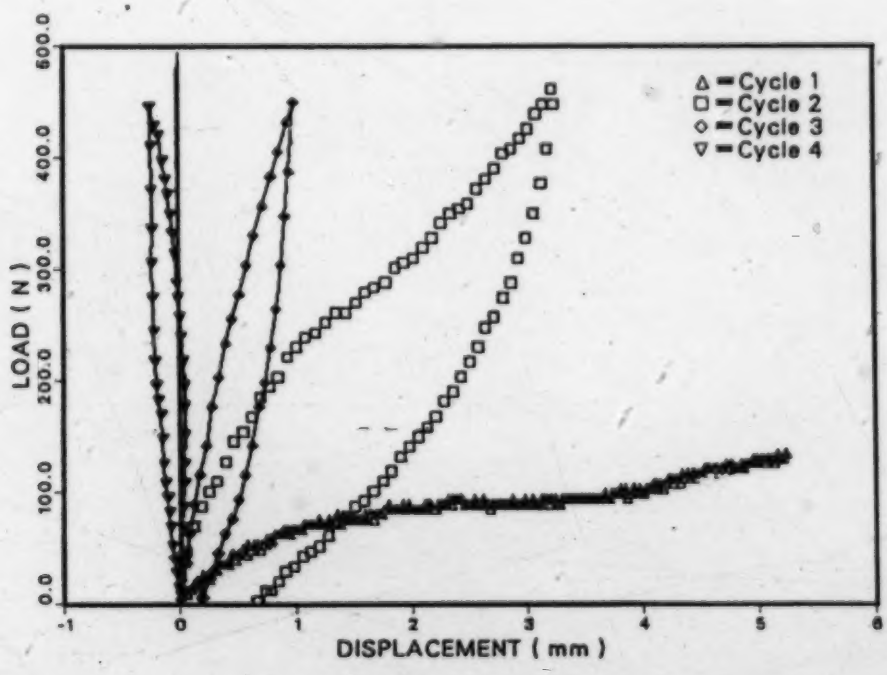


FIGURE 7.7. VERTICAL FRACTURE DISPLACEMENT FOR CYCLES 2, 3 AND 4

fracture closed very slightly in flexion until approximately 200 N when it began to open in extension to maximum of approximately 0.3 mm. The load rate was slightly higher than for the previous cycle. High resistance to load with negligible fracture site displacement indicated the load was essentially over the fracture hinge point or fulcrum. Having found the fulcrum, moment arms for the 1st, 2nd and 3rd cycles were determined to be 95 mm, 55 mm and 15 mm respectively, providing corresponding bending loads of 9 Nm, 25.5 Nm and 7 Nm. Compression bending cycles 5 to 9 were performed using identical moment arms of 55 mm and a load of 470 N (bending moment of 25.5 Nm) which was more than twice in vivo load conditions. Figure 7.8 shows the load rates. Overload conditions occurred because the fulcrum location was not known until testing was completed. Four minute recovery intervals were allowed after cycles five and six. Cycles 8 and 9 were performed after complete removal and reinstallation of the specimens. This included removal of the end caps and transducer. Load rates for cycles 6 and 7 were identical and showed no deterioration but were steeper than the cycle 5 indicating some initial conditioning. Cycle 8, performed immediately after the end caps were removed and reinstalled, practically shadowed cycle 5 indicating high experimental reproducibility in spite of reapplication of the end cap. Figure 7.9 shows vertical displacement for cycles 5 to 9 and the horizontal displacement for cycle 5. Horizontal displacement curves for cycles 6 through 9 are not shown as they are identical with cycle 5. Each cycle exhibited a fracture site closure of 3.3 mm except cycle 9 which had a smaller closure of 2.7 mm. Cycle 9 is markedly different due to human error in precise relocation of the end cap which presumably resulted in a

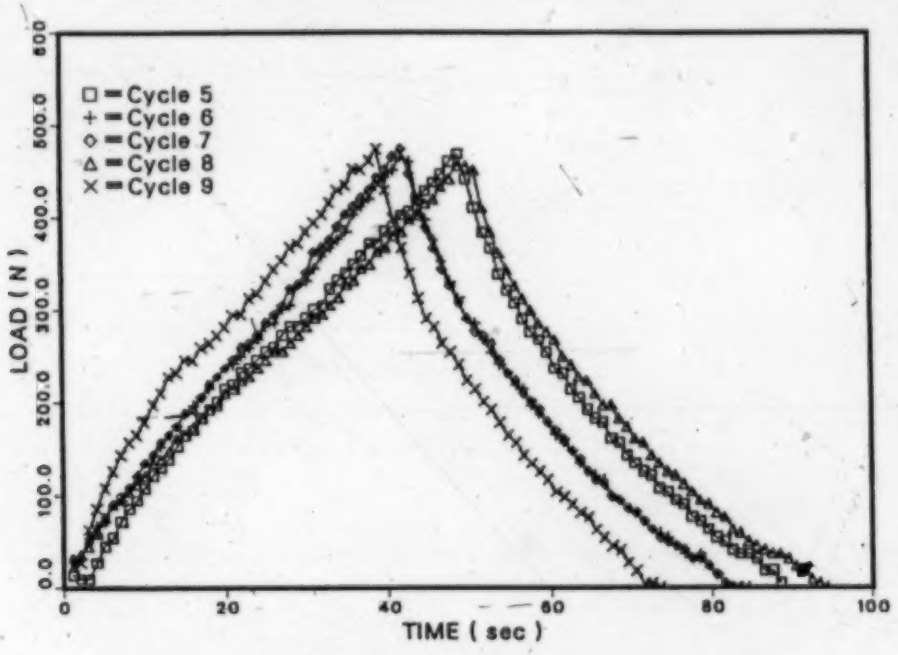


FIGURE 7.8. COMPRESSION BENDING TEST LOADING (CYCLES 5 - 9)

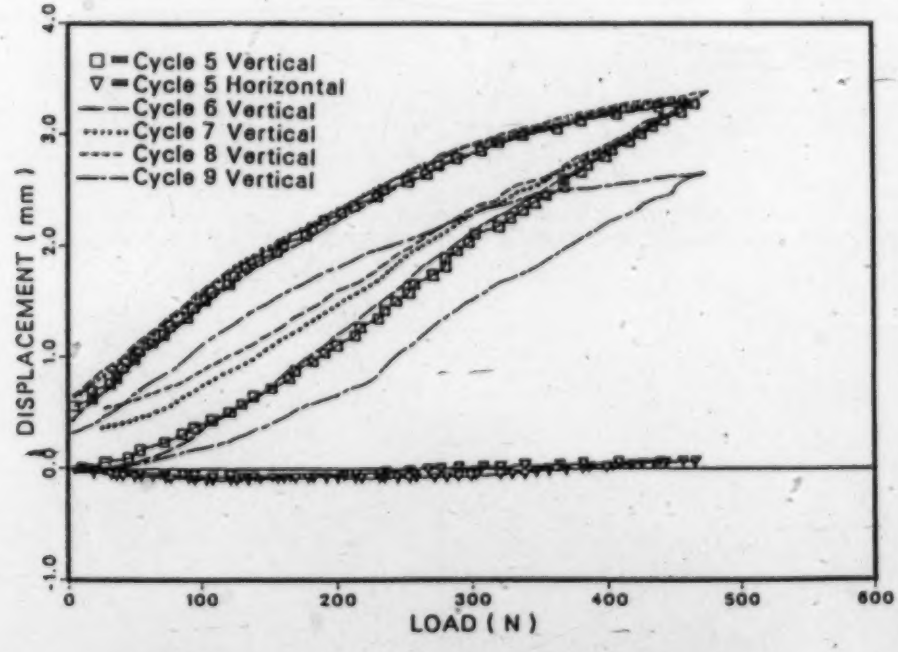


FIGURE 7.9. COMPRESSION BENDING TEST FRACTURE DISPLACEMENT (CYCLES 5 - 9)

shorter moment arm resulting in a smaller fracture displacement and greater load rate.

7.3. Axial Compression Test (cycles 10 to 16)

The specimen was subjected to seven axial compression cycles immediately following the initial compression bending tests. Fixed end conditions were introduced to ensure pure translational loading. Five identical axial load cycles were applied followed by two cycles in which the specimen was removed from the loading device, end caps and measurement transducer and then reinstalled. A preload of 700 N, modelling a person lying down [9], was applied at the beginning of each cycle and held for four minutes to allow creep. Loading was applied quasi-statically to 1900 N, modelling a person sitting with twenty degrees forward flexion. Figures 7.10 and 7.11 show loading rates and displacement/load results for all cycles. A significant difference is shown between cycles 10 and 11 while cycles 11, 12, 13 and 14 are similar. This indicates significant conditioning during the first load cycle and good uniformity for subsequent load cycles which were not reduced below the prescribed 700 N preload. After removal and replacement of the specimen, cycle 15 was similar to the cycle 10 indicating excellent reproducibility and low specimen degradation. However, repeating specimen removal and replacement prior to cycle 16 produced a slightly higher load rate. Figure 7.11 shows vertical displacement for cycles 10 through 16 and horizontal displacement for cycle 10 only as horizontal displacement was similar throughout compression cycles 11 to 16 and is not shown. The compression test showed a slight increase in gross displacement during each repetitive load. However, cycle 15

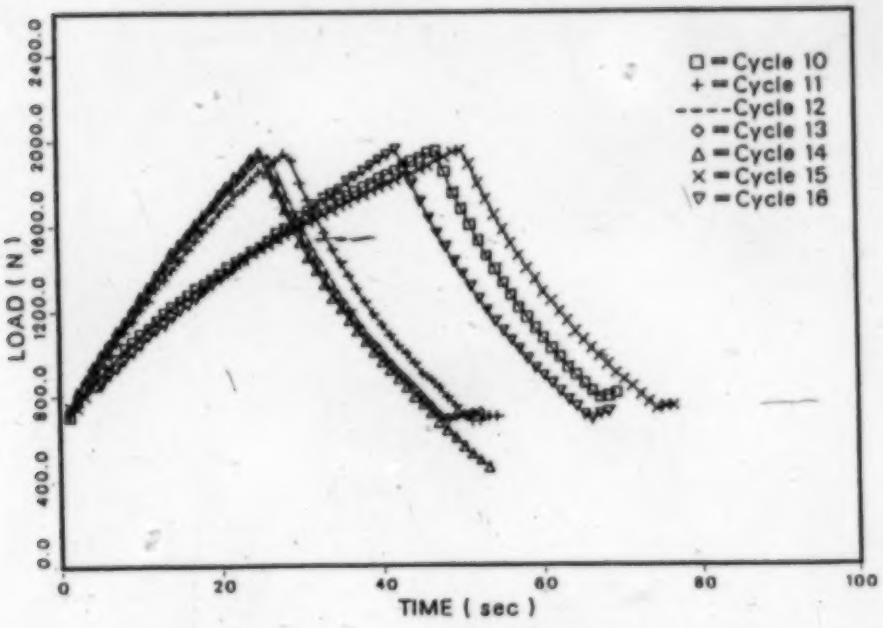


FIGURE 7.10. COMPRESSION TEST LOADING (CYCLES 10 - 16)

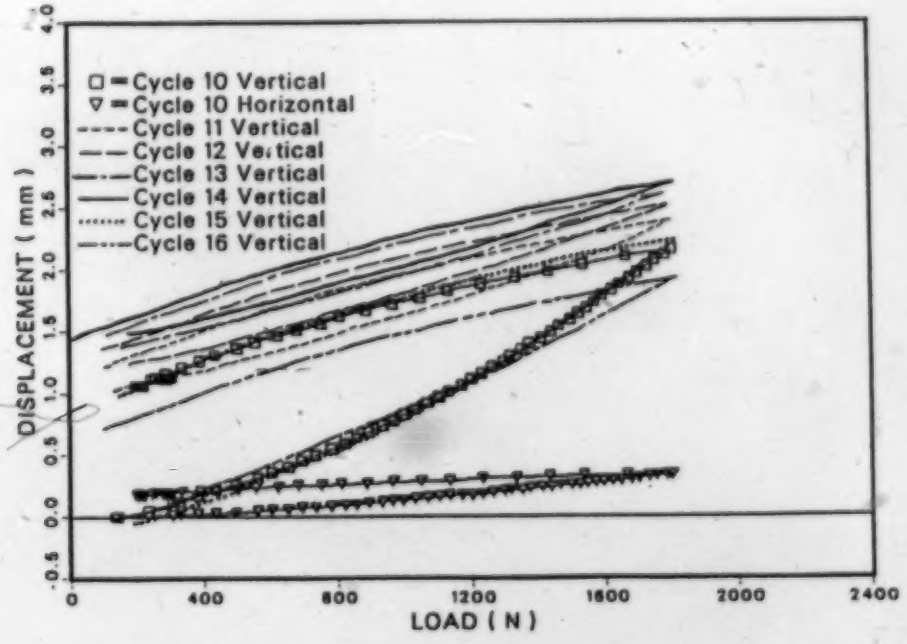


FIGURE 7.11. COMPRESSION TEST FRACTURE DISPLACEMENT (CYCLES 10 - 16)

recovered fully and duplicated the first cycle (cycle 10) following the first removal and replacement of the specimen endcaps and transducer. Some indication of degradation after the second specimen removal and replacement (cycle 16) was evident, similar to compression bending results.

7.4. Torsion Test (cycles 17 to 24)

Eight cycles of torsion loading to +/-12 Nm were performed next, however data for cycles 17, 18 and 19 was lost due to equipment problems. Unfortunately the torsional loading mechanism required manual control of the rotational feed rate introducing some variation to load rates shown in Figure 7.12. The maximum vertical displacement (Figure 7.13) was approximately 0.2 mm and horizontal displacement approximately 4 mm (+/-2 mm) over the entire load range. Conditioning effects due to the first three lost cycles is unknown but lateral displacement in torsion cycles 20 and 21 (Figure 7.14) are essentially identical. The specimen was overloaded due to manual testing machine feed control error during positive loading of cycle 22. This overloading may have affected the results of cycles 23 and 24 by over extending the fracture as the loading trend on the positive portion of the cycle (bottom right quadrant of the graph) shows a marked departure although the left side trend shows no significant difference. The specimen was removed and replaced prior to cycles 23 and 24. Little variation was shown between test cycles aside from an overload during cycle 22 which caused a significant increase in displacement from 2 mm to 2.3 mm for one half of the cycle which indicated the fracture site had suffered

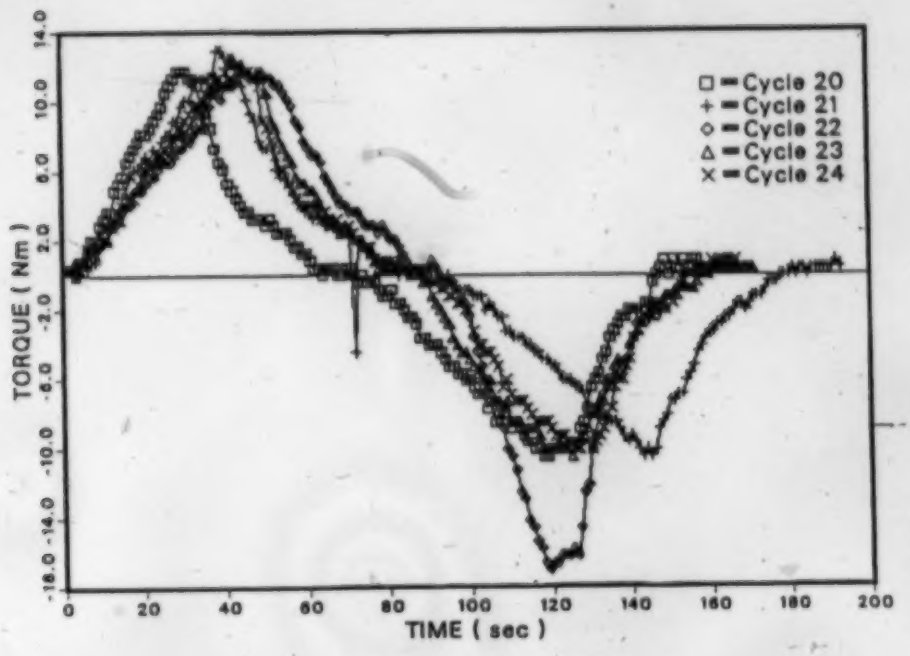


FIGURE 7.12. TORSION TEST LOADING (CYCLES 20 - 24)

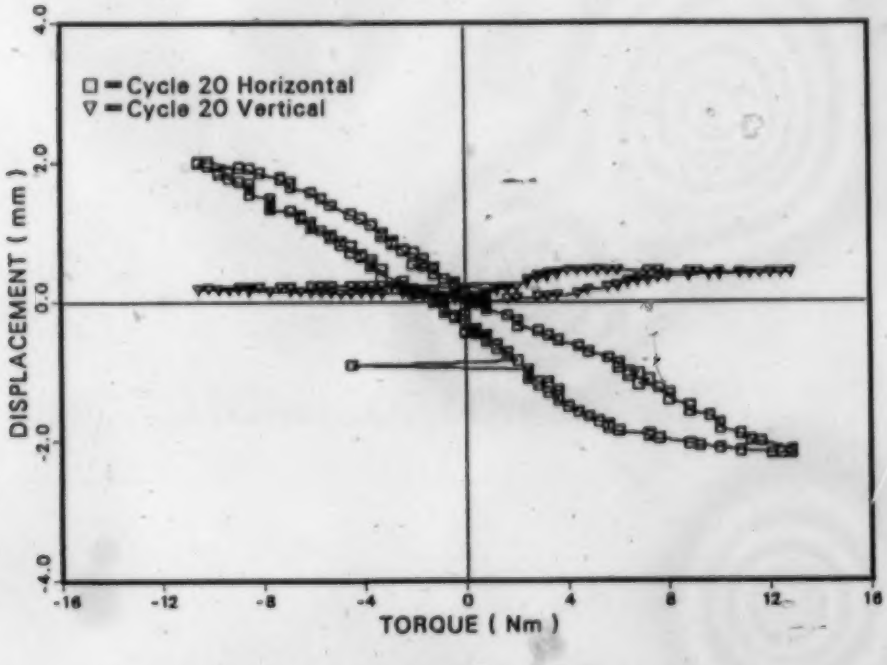


FIGURE 7.13. TORSION TEST FRACTURE DISPLACEMENT (CYCLE 20)

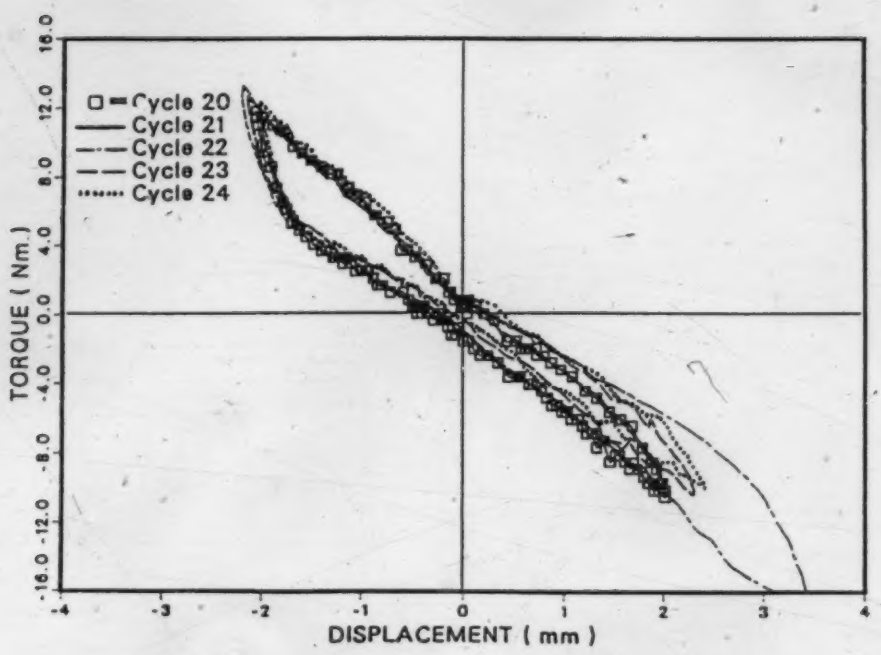


FIGURE 7.14. TORSION TEST LATERAL DISPLACEMENT (CYCLES 20 - 24)

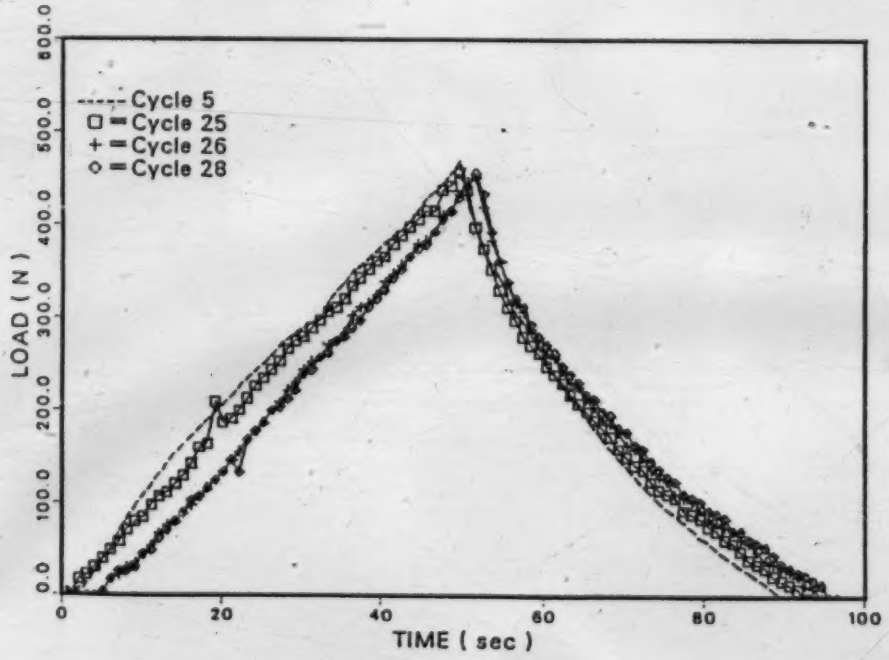


FIGURE 7.15. COMPRESSION BEND TEST LOADING (CYCLES 5,25,26,28)

further damage. The torsion test shows excellent repeatability despite the requirement of manual control of the rotational feed rate.

7.5. Final Compression Bending Test (cycles 25 to 28)

Four cycles of compression bending were performed immediately following the torsion tests. Displacement data from cycle 27 was lost due to equipment problems. Figure 7.15 shows load rates for the final compression bending cycles (25, 26 and 28) and are compared to compression bending cycle 5, the first cycle of the initial cycle compression bending test. The load rate of cycle 25 was almost identical to cycle 5 showing excellent reproducibility and little specimen deterioration or variation in specimen loading over twenty load cycles. Cycles 26 and 28 were similar to cycle 25 with only slight departure due to conditioning effects following specimen installation. Displacement/load results are also compared with cycle 5 in the initial experiment in Figure 7.16. Maximum fracture site closure was essentially identical in all cycles.

7.6. Summary

Tests were performed to assess the reproducibility provided by the new procedure and to determine the extent of degradation of the spine over eight hours of testing and twenty-eight load cycles. Excellent reproducibility of the experimental setup including complete removal of loading fixtures, end caps and measurement transducer from the porcine specimen has been shown. Careful implementation of in-vivo loading conditions maintained the integrity of the specimen throughout the experiment. The experiment was not performed in a humidity chamber

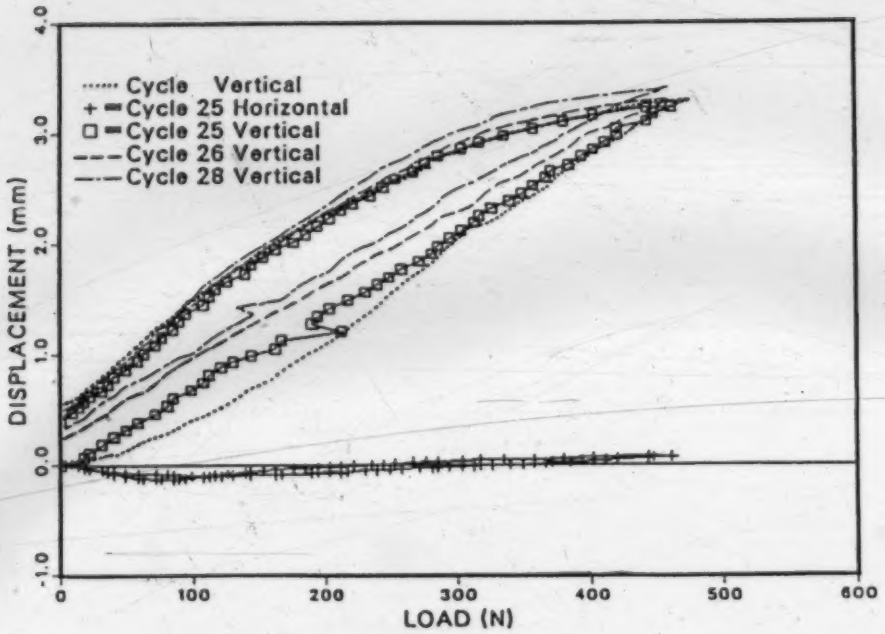


FIGURE 7.16. COMPRESSION BEND TEST FRACTURE DISPLACEMENT (CYCLES 5,25,26,28)

and the specimen was not sprayed with a saline solution to avoid dehydration showing that variables introduced by lack of these conditions are negligible.

Chapter 8. Conclusions and Recommendations

In this study, an experimental method was developed for the evaluation of internal spinal fixation devices. Procedures were introduced for maintenance and preparation of relevant uniform spinal models (specimens). Reproducible fracture creation was addressed and implemented. Accurate measurement of fracture site motion was incorporated, establishing a reliable basis for evaluation and comparison of spinal fixation device performance. Specialized specimen mounting end caps were employed to ensure precise load application and end conditions. All procedures and equipment developed were highly reproducible and economized the time expended in experimental trials. Significant experimental variations experienced in earlier studies were reduced to a minimum in this study.

8.1. Improvement of Experimental Methods and Equipment

Gross discrepencies in specimen size, age and condition has caused large variations in results from spinal fixation experiments. Acquisition of uniform specimens significantly reduced this source of experimental error. Specimen preparation time is significantly shorter than for most other methods. The reduced tedium in the method presented here should reduce the risk of human errors. Complete defect preparation and fracture creation can be performed within one hour. This ensures the specimen is not subject to deterioration. Fracture creation has been another principal source of experimental variation, but with introduction of a reproducible fracture this problem has been substantially overcome. The transducer used in this thesis has

improved accuracy (+/- 0.04 mm) over previous methods of measurement of fracture mobility. Local measurement detects fracture site motion only and excludes soft tissue movement, while global measurement schemes include the effects of soft tissue. Attachment of the loading end cap directly to the instrumented vertebra eliminates variability due to intervening soft tissue. The method of loading and fracture site measurement in this thesis permits precise location of the fulcrum and determination of accurate bending moments and loads within the fractured vertebra. Accurate load carrying analysis within the standard fracture provides the ability to thoroughly compare the characteristics of various fixation devices (instrumentation).

Human error in setup and experimentation and variations in surgical application of fixation instrumentation are the primary sources of experimental discrepency remaining in the test method. Meticulous experimental care and attention to detail by the investigator and/or surgeon is paramount to obtaining precise, valid experimental results.

8.2. What is a "Physiological Experiment" ?

During treatment and recovery the orthopeadic surgeon restricts patients to very sedentary activity. They sleep, sit, bend, and take short walks but the patient limits the range of motion and loads on his spine. Based on this, the question is asked: what is a more valid experimental foundation - standardized loads or standardized displacement? Should the range of motion at the fracture site be compared to a range of physiological loading, a range of gross physiological specimen movement at the end caps or both? Both experimental techniques should be incorporated to determine which is more relevant, which gives better

reproducibility and to determine if a difference is noted. Although the fulcrum of an in vitro specimen may be precisely located, it moves with respect to the point of load application because of the flexibility of the specimen. The author recommends the "range of motion experienced at the fracture site" versus "range of motion of the ends of the specimen" test as a means of eliminating this problem. In addition, a complete model of the musculoskeletal structure of the abdomen should be conducted in order to verify the in vitro model and the loads applied to it.

8.3. Experimental Control of Load and Fracture Site Displacement

Using a limit system featuring control of both loading and fracture site displacement would ensure that a test remains relevant during load repetitions or cycles by protecting the fracture site from overloads and excess displacement. Displacement control, performed using transducer measurement feedback ensures the fracture site is not over extended or further fracture introduced. Using the initial vertebral height and the maximum fracture displacement, the vertebra can be reduced to the original height and fracture site displacement used as a control to prevent or determine if further damage has occurred. Further fracture damage can also be monitored with acoustic emission techniques to verify additional damage and subsequent loss of experimental control. Careful application of relevant in vivo loading ensures the integrity of the specimen is reasonably maintained. Overloading should only be performed when testing structural integrity and limits of the experimental apparatus and methods.

8.4. Comparing Three, Five and Seven Segment Studies

Comparison of a three segment spine study to a five or seven segment study is difficult due to the difference in spinal column length. This comparison, however, is required when comparing a Harrington rod to a pedicle screw device. Elimination of unsupported intervening discs (flexible end condition) is critical, especially in compression bending as the disc can be easily overstressed before meaningful in vivo loading is transmitted to the fractured vertebra. End caps ensuring only fixated segments are subjected to loading provides a more valid comparison. Accurate load carrying information at the fracture site will simplify three, five and seven (multiple) segment comparison studies by providing a local rather than global comparison.

8.5. Other Fracture Types and Instrumentation

This study employs only a compression-distraction fracture, but principles applied in developing this fracture can be used to create other fracture types. Measurement of fracture site motion of other fracture types must be addressed to ensure that maximum motion is recorded. Alternate transducer locations may be required especially when evaluating an anterior fixation device. The location of maximum motion must be carefully determined. For example, anterior instrumentation evaluation may require transducer measurement at the spinous processes to acheive greatest sensitivity. This could be done with minor modifications to the existing transducer system. Initial testing (ie. photograhic cross-hair, three transducers) to identify significant motion components and verify points of maximum relative motion between

fractured components and can help simplify and establish a relevant experiment.

8.6. Other Applications

Much of the experimental technique in this thesis (especially end conditions and loading control) can be applied to in vitro scoliosis and kinematic studies. The transducer or multiple transducers may be applied between vertebrae to provide local information to complement a global measurement technique. The effects of static and cyclic loading on long term creep and failure of biological material could be monitored with the transducer system. The transducer system could be implemented in other anatomical fracture studies such as long bone fracture fixation. Ultimately, the experimental technique would be used to validate numerical modelling of a fractured spine with or without an implanted fixation device.

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APPENDIX A. GLOSSARY OF MEDICAL TERMS

anterior (A)	-	the front of a structure or a part facing toward the front.
anteroposterior (A/P)	-	from the front to the back of the body. (often used to describe direction)
burst fracture	-	any fracture that scatters bone fragments
extension	-	the movement by which two ends of any jointed part are drawn away from each other or increases the angle between each other
flexion	-	a movement by certain joints that decreases the angle between two connecting bones
frontal plane	-	plane passing longitudinally through the body from side to side
inferior	-	below a given point of reference, the lower surface or portion of a structure
in vitro	-	isolated from the living organism (occuring in laboratory apparatus)
in vivo	-	occuring within a living organism
kyphosis	-	curvature of spine, convex backwards
lateral (saggital) plane	-	on the side, vertical plane that passes through and divides the body into left and right portions
ligament	-	a band of fibrous tissue that connects bone or cartilages and serves to support or strengthen joints
lordosis	-	curvature of spine, convex forwards
lumbar	-	referring to the part of the body between the chest and the pelvis
posterior	-	referring to or placed in the back of a structure (in the rear of or near the back surface of the body)
process	-	a projection or outgrowth of bone
reduce (reduction)	-	to restore a body part to its usual place after it has been moved (ends or pieces of bone brought back into line)

scoliosis - sideways or lateral curvature of the spine

superior - found above or higher, the upper surface or portion of a structure

thoracic - of or referring to the chest

APPENDIX B. TRANSDUCER DIMENSIONING

Requirements for transducer performance were based on knowledge of behavior of fracture deformation (Chapter 5). Transducer requirements were:

Range	+/- 5 mm
Sensitivity	0.025 mm
Maximum Load	0.125 lb (0.56 N)

Other requirements include separation of biaxial measuring elements and robustness, size and handling characteristics for strength and ease of installation.

A simple cantilever beam with a short sensing element with a shallow cross section was chosen to meet the above requirements. This is shown in Figure B.1 in which end B measures displacement in the z direction. This is sensed by the element at end A on which strain gauges are mounted (parallel to the y axis).

The sensing element is assumed to be much shorter than the moment arm ($l \ll L$). The cross section at end A has width b, depth t and second moment of area I. A deflection δ at end B produces a rotation where $d\phi/dl$ can be approximated by ϕ/l. The basic beam equation can be written:

$$M = \frac{EI\phi}{l}$$

$$= \frac{EI}{l} * \frac{\delta}{L} \qquad \text{(A1)}$$

where $M = PL$

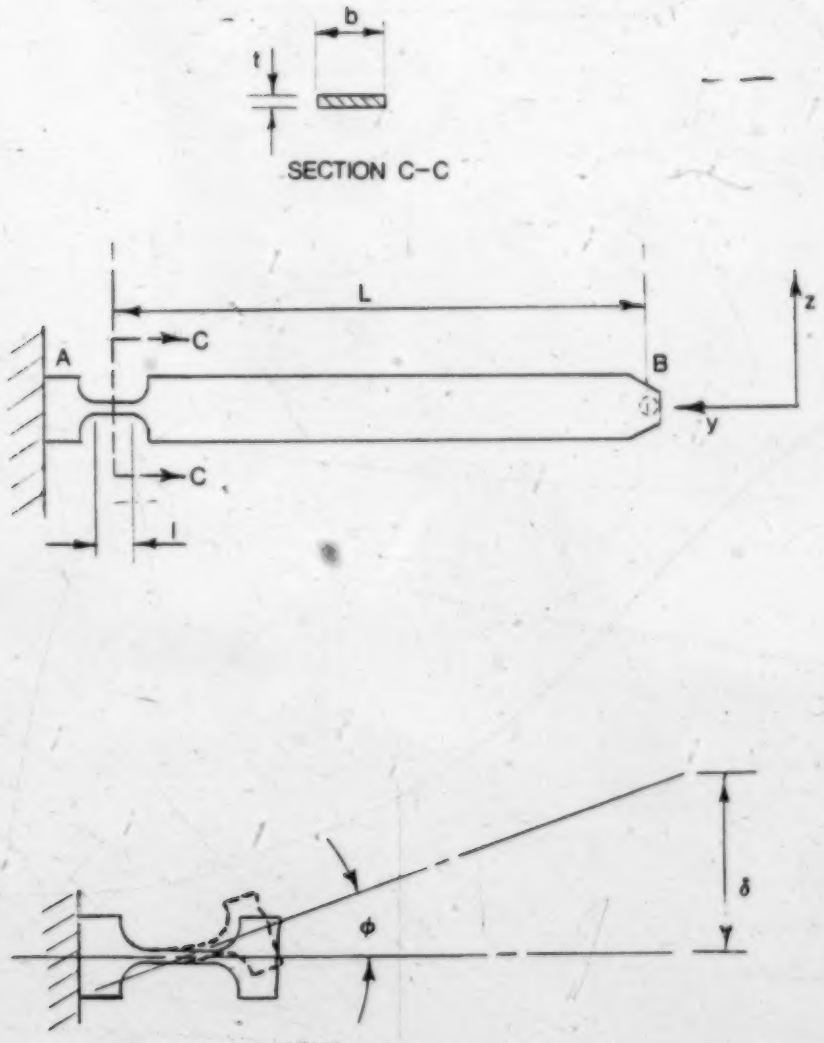

FIGURE B.1. TRANSDUCER MOMENT ARM DETAILS

and P is the force required to cause the deflection (δ) of the end of the beam. The bending stress at the surface of the shallow sensor is

$$\sigma = \frac{M\,t}{I\,2}$$

$$= \frac{PLt}{2I}$$

then $$PL = \frac{2\sigma I}{t} \qquad \text{(A2)}$$

From A1 and A2,

$$\frac{2\sigma}{t} = \frac{E\delta}{1L}$$

Tool steel was chosen for the sensing element because of its high strength (572 MPa yield) and machinability. To minimize the load on the specimen applied by the transducer, the depth (t) was reduced to the minimum value without difficulty (approximately 0.5 mm). A gauge length (1) of approximately 10 mm was selected, based on the minimum space required for strain gauge installation. Using these values, a moment arm length of about 100 mm was obtained. Pairing two such sensors as shown in Figure 5.4, allowed two perpendicular displacement components to be measured with the same moment bar.